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IN THE

Supreme Court of the United States

EVELYN HEINRICH and
HENRY M. SIENKEWICZ, JR.,
Petitioners,

v.

WILLIAM H. SWEET, M.D. and
MASSACHUSETTS GENERAL HOSPITAL,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

In reversing a jury verdict for the subjects of human radiation experiments, the Court of Appeals took its mandate to conduct *de novo* review as a license to make its own judgments and ignored, misinterpreted and retroactively excluded evidence. The question thus presented is:

Whether, in reviewing the trial court's denial of a motion for judgment, the Court of Appeals nullified the historic standard of review adopted by this Court to preserve the right to jury trial (recently reiterated in *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133 (2000)), when it:

1. Ignored probative evidence received after plaintiffs' case-in-chief; and

2. Without finding an abuse of discretion, overruled the trial court as to expert testimony; and

3. Ignored all evidence, including expert testimony and Defendants' own admissions, establishing that the experimental treatment caused the deaths of the subjects; and

4. Invariably interpreted evidence in the light most favorable to the losing party, whenever it could be viewed in more than one way; and

5. Improperly interpreted the jury's general verdict for Defendants on informed consent to be inconsistent with the findings of negligence made by jury and judge, even though Defendants did not raise the alleged inconsistency before the jury was discharged?

PARTIES TO THE PROCEEDINGS

Plaintiffs are Evelyn Heinrich, on behalf of her husband, George Heinrich, and Henry M. Sienkewicz, Jr., on behalf of his mother, Eileen Rose Sienkewicz.

Defendants are Elizabeth Dutton Sweet and Frederick H. Grein, Jr., Representatives of the Estate of William H. Sweet, M.D., and Massachusetts General Hospital.

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Petitioners Evelyn Heinrich and Henry Sienkewicz ("Plaintiffs") respectfully petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit entered on August 27, 2002.

OPINIONS AND ORDERS BELOW

The Court of Appeals' August 27, 2002 opinion vacating the jury verdict for the Plaintiffs on the wrongful death and negligence claims (Pet. App. 1a-35a) is reported at 308 F.3d 48. The order denying rehearing or rehearing en banc (Pet. App. 73a-74a) is unreported. The post-trial memorandum opinion by the trial court (Pet. App. 36a-72a) is reported at 118 F. Supp. 2d 73.

JURISDICTION

The Court of Appeals entered its judgment on August 27, 2002. The Court of Appeals denied Plaintiffs' petition for rehearing and suggestion for rehearing en banc on November 14, 2002. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

The Seventh Amendment provides: "In Suits at common law, ... the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law." U.S. CONST., amend. VII.

STATEMENT OF THE CASE

In 1960-62, Defendants Sweet and MGH conducted radiation experiments on human subjects which eventually led to the deaths of at least nine persons, two of whose survivors were prevailing Plaintiffs in this litigation. In September 1995, Evelyn Heinrich, on behalf of the Estate of her husband,

George, Henry Sienkewicz, on behalf of the Estate of his mother, Eileen, and Rosemary Gualtieri, on behalf of the Estate of her father, Joseph Mayne filed a class action against Sweet, MGH, and others.[1] Second Amended Complaint.[2] [JA 46] Walter Van Dyke, on behalf of the Estate of his father, Walter, was subsequently added as a named Plaintiff. Federal question jurisdiction was alleged. The case was transferred pursuant to 28 U.S.C. § 1404 to the trial court for Massachusetts on September 17, 1997. It was subsequently determined, at Defendants' urging, that this case arises under the Price-Anderson Act (42 U.S.C. § 2210). Therefore, though grounded in state law, the federal court had exclusive jurisdiction. 42 U.S.C. § 2210(n).

As a result of a series of pre-trial and trial rulings, all claims against AUI and Farr were dismissed, the claims of Walter Van Dyke and Joseph Mayne against all the private parties were dismissed; and the claims of George Heinrich and Eileen Sienkewicz proceeded to trial against MIT, MGH and Sweet on negligence, lack of informed consent, wrongful death and punitive damages.

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[1] The other Defendants were Associated Universities, Inc. (AUI) which operated Brookhaven National Laboratories (BNL), a nuclear research facility owned by the Atomic Energy Commission (AEC), Estate of Lee Edward Farr, M.D. (Farr), Massachusetts Institute of Technology (MIT) and the estates of Dr. Shields Warren and Dr. Charles Dunham, who were the federal officials at the AEC responsible for approving and funding human radiation experiments, for injuries caused by such experiments, authorized and funded by the AEC in violation of AEC policy. Eventually the U.S. was substituted for the estates of Drs. Dunham and Warren.

[2] JA refers to the Joint Appendix filed in the Court of Appeals.

The trial commenced on September 7, 1999. After sixteen days of trial, the case was submitted to the jury,[3] which deliberated for seven days and, on October 15, 1999, returned a verdict for Plaintiffs against Sweet and MGH for negligence, wrongful death and punitive damages[4] and for MIT on all counts. The jury awarded Evelyn Heinrich $250,000 in compensatory damages for negligence and $250,000 in compensatory damages and $2,000,000 in punitive damages ($750,000 against Sweet and $1,250,000 against MGH) for wrongful death. The jury awarded Henry Sienkewicz $500,000 in compensatory damages for negligence and $2,000,000 in compensatory damages and $3,000,000 in punitive damages ($1,000,000 against Sweet and $2,000,000 against MGH) for wrongful death.

Post-trial, the court denied class action certification. On February 9, 2000, the Court granted judgment for the U.S. based on its asserted independent contractor defense.

Motions for reduction of the verdict and to set aside the verdict were filed by MGH and Sweet. The motion to reduce the verdict was granted, as the court held that the case was governed by the Massachusetts wrongful death law in effect when the deaths occurred, rather than the law in effect when suit was filed. The Rule 50 motion for judgment was denied, the trial court ruling from the bench that "[t]he evidence is

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[3] The nine jurors included two business managers, three medical secretaries employed by hospitals (one had worked at MGH), one software engineer, two salespersons, one nanny and a retiree whose wife is employed in the medical field.

[4] As the statute of limitations question was presented to the jury on legally correct instructions to which Defendants did not object then or subsequently, the trial court recognized that "...the jury found that the statute of limitations had been tolled." Pet. App. 53a.

sufficient to support each of the causes of action which were submitted to the jury."

While the trial judge did not explain his rationale for denying Defendants' motion for judgment in the course of ruling from the bench, his reasoning as to Defendants' principal grounds was clearly set forth in other rulings, before and after denying the post-trial motion for judgment. For example, during the course of argument regarding the court's proposed jury instructions, on October 6, the trial judge expressed his complete agreement that Plaintiffs were not required to show that Defendants hastened the deaths of Heinrich and Sienkewicz in order to establish liability, but that the amount by which the life of each was shortened was a measure of compensatory damages for wrongful death. [JA 2554-5] The next day, the trial court instructed the jury that if it found liability for wrongful death, the amount of Plaintiffs' loss was to be measured by hastening of death, but "if the person would have died at the same time anyway, there's no damages under wrongful death, no damages at all." [JA 2610-11] Defendants did not object to the instructions on wrongful death liability (which did not include "hastening" as an element) or damages (which did). Likewise, Defendants did not assert any alleged inconsistency in the verdicts before the jury was discharged.

The trial court's findings of fact, made in the course of ruling on MGH's charitable immunity defense, further explain the trial judge's conclusion that the evidence was sufficient to support the jury's verdict on negligence. The Court held, in essence, that Defendants had consciously decided to go forward with their experiment on human subjects despite their definite knowledge that they lacked information that they knew was essential to avoid causing harm. Pet. App. 68a.

A timely motion to alter the judgment pursuant to Rule 59(e) of the Federal Rules of Civil Procedure was filed by

Plaintiffs seeking to reinstate the full amount of the jury award and to obtain prejudgment interest. The motion was denied and the appeals followed.

After briefing and argument, the Court of Appeals vacated the judgments in favor of the Plaintiffs, holding that their proof was insufficient to support verdicts for wrongful death (Pet. App. 19a) and negligence (Pet. App. 20a-31a), and that the verdict for Defendants on informed consent was inconsistent with the verdict for Plaintiffs on negligence. Pet. App. 32a. Plaintiffs timely petitioned for rehearing and/or rehearing en banc, because the opinion by the Court of Appeals had ignored a wealth of evidence supporting the jury's verdicts. Although Judge Torruella was "of the opinion that neither the facts nor the law support the panel's decision to vacate the jury's verdict," the petition was denied on November 14, 2002. Pet. App. 74a.

REASONS FOR GRANTING THE WRIT

The opinion by the Court of Appeals nullifies a long and consistent line of this Court's pronouncements, including *Reeves*, that limit the authority of reviewing courts in order to protect the constitutional guarantee of trial by jury. The Court of Appeals' opinion demonstrates a cavalier attitude–rather than the deference mandated by the Constitution–toward the factual findings made by the jury. The opinion makes it clear that protecting reputations is more important than preserving the Seventh Amendment. While paying lip service to decisions respecting the sanctity of trial by jury, the Court of Appeals exposed its clear bias in favor of preserving both the professional reputations of Defendants and the unfettered ability of medical researchers to conduct human experimentation without regard to legal liability for their failure to follow the ethical standards of their own profession. It could only achieve these ends by eviscerating the jury's decision and

distorting the evidentiary record. For example, in analyzing negligence, the court disregarded testimony by Defendants' employees that they had knowingly violated the standard of care in the interest of expediency, and engaged in circular reasoning by treating Defendants' approval of their wrongful conduct as proof that Defendants "complied with the prevalent standard of care." Pet. App. 31a. In analyzing causation for the wrongful death count, the court never mentioned the competent expert opinion evidence adduced by Plaintiffs, much less Defendant Sweet's concession, in an article he authored, that Plaintiffs' deaths were caused by the experimental medical procedure he devised and administered.

To the extent the Court of Appeals considered Plaintiffs' expert testimony at all, it busied itself with improperly second-guessing the trial court's performance as a "gate-keeper" (regarding testimony as to the standard of care) and using the alleged absence of evidence of hastening death as a basis to find there was no liability, even though the unchallenged jury instructions made clear that hastening of death was an issue related solely to damage. Finally, the Court of Appeals incorrectly asserted the defense verdict on informed consent was inconsistent with the jury's finding of negligence.

In setting aside the verdict, the Court of Appeals effectively (unless this Court grants certiorari) denied Plaintiffs their right to trial by jury, by substituting its own independent conclusions for those of the trial judge and jury on critical, fact-dependent issues.

Petitioners are aware that this Court rarely grants petitions when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law, but these are not the errors we assert. The factual findings by the jury and the trial judge were correct and as the trial judge said, the evidence supported those findings. In conducting its

very limited review of the factual findings of the jury, the Court of Appeals ignored its constitutionally mandated obligation to review "*all* of the evidence in the record" and instead selectively summarized the record so as to omit evidence supporting the verdict. As evidenced by its description of its own function and by its actions herein, the First Circuit has adopted a view of *de novo* review that is at odds with the teachings of this Court, the other circuits and the Commonwealth of Massachusetts. Under its parsimonious interpretation, the Court of Appeals is not obliged to consider all of the evidence, and it is free to substitute its own conclusions for those of the jury. In doing so in this case, the court did not merely misapply the law, it violated it.

There always has been tension between the Seventh Amendment's guarantee of trial by jury and the constitutional guarantee of due process–the source of the courts' power to overturn jury verdicts. In many cases, but not this one, it is difficult to strike the balance. This case provides a clear example of an appellate court overstepping the bounds imposed by the Constitution, and so a golden opportunity exists for this Court to address and provide needed guidance on a persistent issue affecting the rights of litigants everywhere.[5]

Petitioners submit that this Court should grant certiorari in order to stop further severe erosion of the right to trial by jury and to justify the public's confidence that this Court will continue to protect that right. When an appellate court reverses the trial judge's denial of a motion for judgment and vacates the jury's verdict, it knows that for all practical purposes it has "the last word" on the sufficiency of the evidence. In that

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[5] For example, consider the well-known reluctance of courts in some circuits to permit juries to decide discrimination cases, even after this Court in *Reeves* painstakingly elucidated what had seemed to be its perfectly clear holding in *St. Mary's Honor Center v. Hicks*, 509 U.S. 502 (1993).

situation, it has a duty at least to consider all of the evidence, and to do so with a view toward preserving the verdict. When, as here, it is readily apparent that the appellate court has totally disdained that duty, then the need for this Court to exercise its power is clear and compelling.

A. Review Is Warranted to Insure that the Constitutional Guarantee of Trial by Jury Will Be Preserved

The Petitioners are the two Plaintiffs who established at trial that their loved ones died of radiation necrosis, through Defendants' negligence in the 1960-62 Boron Neutron Capture Therapy (BNCT) trials conducted by MGH and Dr. Sweet at an MIT reactor. In BNCT, a compound containing boron-10 would be injected into the bloodstream supplying the brain. There was a basis to believe that this compound would concentrate in greater quantity in the tumor tissue than it would in the blood vessels of the brain, although, as seen below, the extent of that preferential distribution was not known. All the cells containing boron, including the healthy blood vessels and blood in them, would then be exposed to a neutron beam produced by a nuclear reactor. When the neutron beam interacted with the boron-10, a fission reaction would occur and destroy any cells containing boron-10, including the blood vessels. It was hoped that higher levels of boron in the tumor would allow a lower dose of radiation to be applied to the head, thus killing the tumor without doing substantial damage to the blood vessels and other healthy tissue containing the boron. The evidence considered by the jury but ignored by the Court of Appeals included proof that Defendants administered BNCT at the MIT reactor to eighteen patients, none of whom survived. Post-mortem examination of fourteen of the subjects revealed that nine died, not from cancer, but from radiation necrosis. This condition resulted because the cells in the walls of their healthy blood vessels retained sufficient boron and therefore

were exposed to the same lethal nuclear reaction that was intended to kill the tumor cells.

The risk of this outcome was understood by Defendants. The Defendants knew that it only could be avoided by finding a boron compound that would be retained in tumor cells in substantially larger quantities than in the blood vessels, and by administering a precisely measured dose of radiation to a precisely circumscribed area. Defendants did neither. Before beginning trials on human subjects, Defendants were fully aware that they did not know whether their compound was correct, or whether their radiation doses were accurately measured, yet they decided to forge ahead, in the interest of saving time. As they later admitted, Defendants anticipated that the autopsies of their experimental subjects[6] would reveal whether it had been safe to proceed.

The Court of Appeals stated its belief that "[w]hat is at stake is the medical treatment of two patients and the professional reputations of individuals and institutions based on services performed over four decades ago." Pet. App. 35a. Petitioners submit that this is incorrect. What is at stake is the right of litigants to a trial by jury.

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[6] In the interest of science, Dr. Sweet was determined to study the brains of the subjects. In the case of George Heinrich, who died at a nursing home, Sweet arrived at the funeral home just before the wake was to start, and persuaded Mrs. Heinrich to let him remove her husband's brain.

B. The Court of Appeals has Adopted a Standard that Disregards the Constitutional Requirement that It Consider All of the Evidence Supporting the Verdict and Defer to the Jury's Findings

The power of a court to overturn the verdict of the jury is limited by the Seventh Amendment. Consequently, this Court has reiterated the standards which must be met before a jury verdict may be vacated on a motion for judgment:

> ...a court should render judgment as a matter of law [only] when 'a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue.'

Reeves, 530 U.S. at 149, *quoting* Fed. Rule Civ. Proc. 50(a) (emphasis added).

> It therefore follows that, in entertaining a motion for judgment as a matter of law, the court should review all of the evidence in the record.
>
> * * *
>
> "In doing so, however, the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.
>
> * * *
>
> 'Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.' Thus, although the court should review the record as a whole, it must disregard all evidence favorable to the moving

> party that the jury is not required to believe.... That is, the court should give credence to the evidence favoring the nonmovant as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.'

Id., at 150-151 (emphasis added, citations omitted).[7]

The Court of Appeals' description of its role, by contrast, reveals much less enthusiasm for the sanctity of jury verdicts. While claiming that it operates with a view toward preserving verdicts, it is silent about its obligations to consider all of the evidence and to defer to inferences the jury could have made, nor does it foreswear weighing the evidence. To the contrary, it hints at a willingness to be selective in its consideration of the evidence, to substitute its own judgments for those of the jury and to take a crabbed view of the limits on its authority to overturn jury verdicts, when it announces its illegally narrow standard of review: "we must affirm unless the evidence was 'so strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them." Pet. App. 14a.

The court's actions in this case confirm that it believes it is permitted to ignore evidence favorable to the prevailing party and to substitute its own conclusions for those of the jury, whenever it is offended by the jury verdict.

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[7] The law of Massachusetts, which governed the case is entirely consistent with *Reeves*. See *Lally v. Volkswagen Aktiengesellschaft*, 698 N.E.2d 28,34 (Mass. App., 1998).

C. In Reviewing the Denial of Defendants' Motion for Judgment as to Negligence, the Court of Appeals Violated the Constitutional Standard by Failing to Consider Any of the Evidence Adduced After Plaintiffs' Case-in-chief, Even Though It Fully Supported the Jury's Verdict that Defendants Were Liable for Negligence

The Court of Appeals said that the relevant standard for judging negligence in this case was that used by Dr. Fager: whether, in the context of his time and place, Dr. Sweet "maintained the acceptable methods of practice of neurosurgery." Pet. App. 30a. In so holding it totally ignored Plaintiffs' theory of the case as recognized by the evidence presented, the trial court's instructions and findings, and the findings by the jury.

Plaintiff's theory of the case was not that Dr. Sweet and MGH performed BNCT in a way that deviated from the standard of care for that procedure, much less the standard of care for neurosurgeons performing proven treatments, but that they violated the standard of care for conducting human experiments. They chose to use BNCT when they were well aware that they had no basis to believe it would be therapeutic and had ample reason to believe it would create grave danger for those subjected to it.

It was in this context that the trial judge, when making post-trial findings regarding the defense of charitable immunity, concluded that the conduct of the Defendants was negligent.

> "[T]he Court finds that during the treatment of both Heinrich's and Sienkewicz's decedents, Sweet had actual knowledge of the imprecision of the localization of the boron injections to the

> cancerous brain tissue and the related imprecision of the neutron radiation, with the result that unacceptably high degrees of radiation necrosis were occurring in these and other of his patients. In short, Sweet well knew during his care of these patients that his BNCT treatments were not helping them, and, in fact, were causing severe side effects unrelated to the progressive effect of the fatal brain tumors. He pressed ahead anyway, believing in complete good faith that such experimentation on dying patients held out hope for other cancer victims.[8] However praiseworthy his goal, his conduct with respect to the patients involved here was, as the jury found, negligent."
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> * * *
>
> "[B]y negligently persisting with boron injections after all hope of extending the lives of his patients or alleviating their suffering had vanished, Sweet violated that cardinal principle of the Hippocratic oath, 'First, do no harm.'"

Pet. App. 71a (emphasis added).

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[8] In a footnote, Judge Young observed that "The most poignant [example] of Sweet's medical hubris is found in the testimony of Marie Denning, Eileen Sienkewicz's sister. She testified that she visited her sister in Mass General shortly before the latter's death. She found her sister struggling feebly against the nurses, begging them not to give her any more boron neutron injections. ***Marie Denning went to see Dr. Sweet and asked him to discontinue the treatments.*** His response was to say "Your sister's been through a lot and for the good of mankind . . . this will help." Pet. App. 68a, n. 11.

And, it was in this context that Plaintiffs produced volumes of evidence, including the contemporaneous writings and subsequent admissions by Defendants themselves and their research team captains which revealed that, *before and during* the BNCT trials, Defendants fully recognized they lacked the essential information to determine whether the treatment would more likely help or harm the patients. Some of the strongest evidence, compelling a finding of negligence, consisted of admissions by members of the BNCT team who testified in the defense case. The Court of Appeals never mentioned it.

In its zeal to protect the "professional reputations of individuals and institutions" the court of appeals dismisses this Court's mandate in *Reeves* to "review all evidence in the record" and, ignoring the evidence admitted in Defendants' case, finds Plaintiffs failed to prove the relevant standard of care. Defendants' concessions alone, even without the evidence from Plaintiffs' experts (see the next section) meets the *Reeves* requirement of a "legally sufficient evidentiary basis" from which "reasonable inferences" can be drawn to support the "reasonable jury" finding of negligence.

The crucial information which Defendants needed to have a reasonable possibility that BNCT would do more good than harm depended on having a basis to believe that they had chosen the proper boron compound at the proper dose, which when injected into the blood stream of the patient, would concentrate sufficiently preferentially in the tumor of the brain such that irradiating the entire head would not also kill the blood vessels and kill the patient. Dr. Gordon Brownell, chief physicist for the BNCT experiment, testified it was "absolutely essential" to measure both the ratio of boron in the tumor to boron in healthy brain tissue, and to measure the amount of radiation in the neutron beam. [JA 1881-82] The chief chemist on the experiment, Dr. Soloway, admitted that without an appropriate [boron] compound, BNCT not only would not be

therapeutic, but it would kill healthy brain and blood vessel tissue. [JA 2319]

Thus, Defendants' experts recognized what they needed to know to proceed with BNCT. Tragically, they also conceded they did not calculate the appropriate dose of boron before using BNCT on Plaintiffs' decedents, and that the radiation level to which they would be subjected was based on a boron level assumed or estimated by others. [JA 1883-84] Just weeks before the commencement of the BNCT experiments at MIT[9] Dr. Brownell conceded that "by far the greatest unknown factor concerns the biological effects of this type of massive dose on boron-containing tissue," and that they could not find out any more about that unknown factor without experimenting on humans. [JA 1907-08][10] Why did Defendants proceed even though they knew they had no basis to believe BNCT would do more good than harm? In Dr. Brownell's words because "We might as well go ahead and experiment on patients because we weren't going to get an answer to what we didn't know for decades to come." [JA 1905-07]

The horrific effect of that decision by Defendants was, as Defendants conceded, nine of the eighteen patients in the MGH experiments died of necrosis of the brain–the death of healthy brain tissue caused by BNCT. Pet. App. 27a. Since

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[9] As noted above, BNCT experiments had been conducted on dozens of others, with the participation of Dr. Sweet, at a reactor at Brookhaven, but none of these experiments had been successful.

[10] On November 2, 1960 (two weeks before BNCT began), Dr. Brownell reported that the boron levels wouldn't be measured, only inferred. [JA 1899-1900] Even reasonable estimates could not be made unless the same compound used at the craniotomy for tumor excision was later used at BNCT. [JA 2028] For Heinrich and Sienkewicz, the boron compound used at the craniotomy was not the same one used at BNCT. [JA 2023-24, 1014, 2021-22]

Defendants 1) conceded that prior to the experiments they knew it was essential, in order to avoid killing patients, to know the amount of boron in healthy brain tissue and to know the amount of radiation which would be delivered to that tissue and 2) conceded they did not know the answer to those questions prior to the BNCT experiments, it was more than reasonable for the jury to conclude that the deaths of Heinrich and Sienkewicz caused by BNCT were the result of Defendants' breach of the standard of care for human experiments.

The Court of Appeals compounded its legal error, of ignoring this evidence from the Defendants' part of the case on the standard of care, by committing an equally indefensible moral error. It exonerated Defendants' from their role in the death of Mrs. Sienkewicz and Mr. Heinrich not only to save their reputations, but also to endorse the expediency that unless a patient can prove there was a preferable option available, where medical science cannot advance without using dying patients as test subjects, the use of those patients is acceptable. Pet. App. 22a, n. 8. ("No evidence was ever submitted that there was any way of achieving greater clarity about these points other than through human subjects.") This ill-conceived excursion into the field of medical ethics was, not surprisingly, unsupported by any evidence in the record in this case or anywhere else in the civilized world.

D. In Reviewing the Denial of Defendants' Motion for Judgment as to Negligence, the Court of Appeals Violated the Constitutional Standard by Improperly Reversing the Trial Judge's Rulings on Admissibility of Expert Testimony

The trial court is charged with acting as a "gatekeeper" regarding expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The role of the of

the court of appeals is restricted to reviewing for abuse of discretion. *General Electric Co. v. Joiner*, 522 U.S. 136 (1997). The record in this case reveals that the trial judge was scrupulous in attending to his gatekeeping duties, carefully limiting experts to testimony that was competent and relevant to the precise questions that were before the jury. For example, the trial judge refused to allow testimony from Plaintiffs' experts regarding the standard of care unless those experts explicitly testified to the standard of care that prevailed during 1960-62. Testimony that he determined to be in any way deficient was not allowed. Nevertheless, the Court of Appeals substituted its own judgment for that of the trial court as to the form of expert testimony, so as to retroactively exclude it. In doing so without demonstrating an abuse of discretion, it exceeded its authority and deprived Plaintiffs of their right to trial by jury.

Plaintiffs elicited testimony from Dr. Junck, an expert in neurology and neuro-oncology, showing that Defendants violated the standard of care in the manner in which they conduct human experimentation. He testified that Sweet and MGH acted inappropriately in performing human experiments on Heinrich and Sienkewicz [JA 985-86], that they had no reasonable expectation that the BNCT would be safe or therapeutic [JA 986], and that the problems discovered with BNCT before the experiments were performed on Heinrich and Sienkewicz were not adequately addressed. [JA 986-87, 1021]

Specifically, Dr. Junck testified that because the boron injections given apart from the BNCT had no conceivable therapeutic value, but were only administered for purposes of research, Defendants acted inappropriately and irresponsibly. [JA 987] Regarding the administration of the BNCT itself, Dr. Junck testified to his opinion that Defendants acted irresponsibly, because they proceeded without laying adequate groundwork. Defendants knowingly exposed their subjects to

the risk of harm by performing BNCT without establishing a means to measure the dose of radiation being administered and without having found a boron compound of acceptable toxicity. [JA 988-89, 1018-21, 1022-23]

Dr. Grodin also identified specific breaches of the standard of care in Defendants' decision to conduct the BNCT experiments on human subjects:

> There was no evidence that there was any...potential benefit to the individual terminally ill subjects and there was significant evidence of harm, cell death due to necrosis, and therefore it was my opinion that in weighing the risks against the benefits that the risks outweighed the benefits and therefore...the research should not be conducted.

[JA 2406-08]

The Court of Appeals faulted both the wording and the form of the questions put to Drs. Junck and Grodin.[11] In doing so, it repeated its error of viewing BNCT as medical care conducted within a recognized specialty :

> "First, we think the question put to Dr. Junck was wrong. Its highly suggestive emphasis on acting "responsibly" and its prejudicial reference to "human experimentation" did not concern a standard of care for medical treatment. Second, the form of the question was incorrect and did not lead to the required information. While the standard of care

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[11] The Court of Appeals assigned the same error to the testimony of Dr. Grodin. Pet. App. 26a.

> question need not be formulaic and some leeway is allowed, [citations omitted] we think this question was inadequate to tie Dr. Junck's opinion to the standard of care for a specialist like Dr. Sweet in 1960-61."

Pet. App. 23a-24a (emphasis added)

The trial judge was well within his discretion to permit the questioning as recited above, because he correctly apprehended that this case is about human experimentation and is not about standard treatment within the specialty of neurosurgery (a concept that eluded the Court of Appeals).[12] The issue for the jury was not whether Dr. Sweet and MGH employed the requisite skill in conducting BNCT, but whether it was proper to attempt BNCT at all, when Defendants knew full well that, until more information was obtained, the grave risks of causing harm outweighed the entirely speculative possibility of benefitting the patients.

The Panel was plainly wrong in stating that Drs. Junck and Grodin gave no testimony establishing the standard of care or its breach. They did, but they referred to the standard of care for conducting medical experiments on human subjects. Under that standard, MGH and Sweet were rightfully faulted because they had no reasonable expectation that the BNCT would be safe or therapeutic, they knew that the problems discovered with BNCT before the experiments were performed on

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[12] The Court of Appeals offered the testimony of Dr. Fager, a defense expert, as a model of proper form and substance. However, Dr. Fager's testimony was irrelevant as it was concerned with Dr. Sweet's methods of practicing neurosurgery–not his conduct of experiments. Ironically, the word Dr. Fager used to describe Sweet's practice was "acceptable"– not such a far cry from the word "appropriately" used by Plaintiffs' experts. Pet. App. 30a.

Heinrich and Sienkewicz had not been adequately addressed, and they knew that they were operating in the dark as to all-important factors such as the level and toxicity of Boron and the amount of radiation being given.

Only by ignoring the great bulk of the opinion evidence of Drs. Junck and Grodin, as well as the bases therefor, could the Court of Appeals conclude that neither expert stated the standard of care or that Defendants had breached it. In so doing, the court simply substituted its own judgment for that of the trial judge, without making the required showing that his rulings on the evidence constituted an abuse of discretion.

E. In reviewing the denial of Defendants' motion for judgment as to wrongful death, the Court of Appeals violated the constitutional standard by ignoring all evidence, including expert testimony and Defendants' own admissions, supporting the jury's finding that the treatments negligently performed by Dr. Sweet and MGH caused the deaths of experimental subjects, Plaintiffs' decedents

The Court of Appeals wrongly claimed that the trial court ruled that to establish Defendants' liability for wrongful death, Plaintiffs had to prove "hastening," and do so with expert testimony. This is contrary to Massachusetts law, the trial court's unobjected-to instructions to the jury, and common sense. The opinion of the Court of Appeals simply conflates proof of liability and the measure of damages.

Massachusetts law pertaining to proof of causation is well-settled. It must be demonstrated "that there was greater likelihood or probability that the harm complained of was due to causes for which the Defendant was responsible than from

any other cause." *Nickerson v. Lee*, 42 Mass.App.Ct. 106, 111, 674 N.E.2d 1111, 1113 (1997).[13]

Despite the overwhelming evidence, and admissions, that the harm Plaintiffs complained of– the deaths of George Heinrich and Eileen Sienkewicz–was caused by the BNCT administered by Defendants, this salient fact is never mentioned in the Court of Appeals' decision. Its omission from a decision that is required to consider all of the evidence in the light most favorable to the Plaintiff can only be explained by the fact that the Court of Appeals rejected *sub silentio* the instructions of the trial court on the legal significance of hastening the death evidence, even though Defendants never objected to the instructions. Having failed to object, Defendants were not entitled to relief on appeal, in the absence of a showing of plain error. See Fed. R. Civ. P. 51; *Gray v. Genlyte Group*, 289 F.3d 128, 133-34 (1st Cir. 2002). Yet the Court of Appeals distorted the instruction actually given by the trial judge, incorrectly asserted that its own instruction was not inconsistent with the law, and declared that Plaintiffs had to accept "hastening death" as an element of liability, because they did not object to the trial court's instruction (which did not include that element).

The appellate court's claim that Plaintiffs had to prove hastening of death through expert testimony in order to establish liability for wrongful death is simply absurd. As the trial court made clear, liability depended on causing death, and its instruction on "hastening" death was relevant only to damages. And the evidence supporting a causal relation between the negligence of MGH and Sweet, and the deaths of

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[13] As recited above, the trial court correctly instructed the jury, that Defendants were liable if they caused death, but that the degree of hastening affects the measure of damages.

Mr. Heinrich and Ms. Sienkewicz is direct and overwhelming. Not only did Plaintiffs present expert testimony explicitly stating that BNCT caused the radiation necrosis that killed the Plaintiffs, but Defendants' own records show that Plaintiffs' decedents died from radiation necrosis of their healthy brain tissue, not from cancer. The evidence at trial demonstrated that their radiation necrosis was caused by BNCT. There was no evidence that BNCT also extended their lives.[14] Yet the Panel, which failed even to acknowledge, much less analyze the significance of these facts, wrote: "There is no evidence at all in the record that BNCT hastened decedents' deaths."

As the trial court analyzed the distinction, if a person falling from a 20-story building is shot to death as he passes the tenth floor, the shooter is liable for wrongful death, albeit the measure of damages is only the time it takes to fall the remaining ten floors. [JA 2555] Likewise, in this case where the BNCT by Sweet and MGH killed Plaintiffs' decedents, it follows that Defendants not only caused but also hastened their deaths. In this case, no one disputes that there is evidence that BNCT, not glioblastoma multiforme, caused the deaths. Incredibly, the Panel's opinion ignores this salient fact and all of the evidence supporting it.

Coupled with the absence of expert opinion that BNCT extended the life of Plaintiffs' decedents, it was reasonable for the jury to draw the inference that BNCT, which caused their deaths, also hastened their deaths. By ignoring the competent

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[14] Despite the absence of any expert opinion that BNCT extended life, the Panel goes to great lengths to posit that Mrs. Sienkewicz lasted considerably longer than the median interval following the BNCT. Consistent with its treatment of other issues, however, the Panel ignores all of Plaintiffs' evidence that her earlier craniotomy had left her without tumor at the time of the BNCT, that she had a variant of glioblastoma with a somewhat better prognosis than the other subjects, and that, according to her sister, Marie Denning, she did not improve following the BNCT.

evidence supporting the jury's verdict, the Court of Appeals deprived Plaintiffs of their right to trial by jury.

F. In Reviewing the Denial of Defendants' Motion for Judgment as to Negligence, the Court of Appeals Violated the Constitutional Standard by Interpreting Evidence in a Light Most Favorable to the Losing Party

While the court acknowledged its obligation to interpret evidence in the light most favorable to the Plaintiffs, as prevailing parties, this good intention was swiftly forgotten. Two brief examples illustrate how the court actually interpreted evidence in favor of the Defendants, whenever possible.

First, consider the expert testimony of Dr. Junck. The Court of Appeals incorrectly stated that evidence of record did not establish that his opinions were given with reference to 1960-61, notwithstanding the following exchange:

> Q. [To Dr. Junck:] Now your opinion, of course, is an opinion relative to what people should have known who were working in this area [BNCT] in 1961. And you understand that? A. Yes. [JA 981]

> Q. And the literature you looked at, that's literature that doctors in your position normally look at, and would have looked at back in the early 60's, to find out what the state of knowledge about treating people was. Is that right? A. Yes. [JA 1017]

Next, consider the expert testimony of Dr. Grodin. The Court of Appeals held that his testimony was not tied to the 1960-61 time period. The court actually notes the following

exchange (Pet. App. 26a, n.10), but interprets his testimony to tie only the boron injections, not the BNCT, to the relevant period.

> Q. [To Dr. Grodin:] [D]id you conduct a risk/benefit analysis...of the boron injection experiments? A. Yes.
>
> Q. And did you reach a conclusion as to whether or not those boron injection experiments had a favorable risk/benefit ratio at the time they were conducted in the period 1960-1962?... A. ...Yes, I did....
>
> Q. ... And did you do a similar risk/benefit analysis with regard to the BNCT experiments? A. Yes, I did.... [JA 2406-08]

Considering that Dr. Grodin's testimony related only to the 1960-62 trials in which Plaintiffs' decedents were subjects, which was the only period relevant to the trial, and considering that his analysis regarding BNCT was "similar" to his analysis of the injections in 1960-62, the court's interpretation of the testimony is absurd. At worst, this evidence was susceptible of more than one interpretation, yet the Court of Appeals chose to look at it in the light most favorable to the Defendants, who had *lost* the jury verdict. In doing so, the Court of Appeals deprived Plaintiffs of their right to trial by jury.

G. In Reviewing the Denial of Defendants' Motion for Judgment as to Negligence, the Court of Appeals Violated the Constitutional Standard by Interpreting the Jury's General Verdict on Informed Consent to be Inconsistent with the Finding of Negligence

The Court of Appeals mistakenly theorizes that the jury made a finding of informed consent, when there was no evidence to support such a defense, and no such finding by the jury.[15] The terrible significance of this error is revealed when the court rationalizes that "the fact that Dr. Sweet and MGH prevailed on the informed consent claim also is pertinent to the insufficiency of the evidence to show that Dr. Sweet was in breach of his duty of care to his patients." Pet. App. 31a-32a. The court goes on to explain the supposed "pertinence" as follows:

> Defendants argue that if Heinrich and Sienkewicz were adequately informed about the treatment...and agreed to undergo [it] nonetheless, then Dr. Sweet and MGH cannot be liable for performing the very treatment to which the Plaintiffs agreed. On the facts of this case, we agree with the argument.

Pet. App. 33a. In reality, however, the defense verdict on informed consent cannot offer the support that the Court of Appeals claims. All that the jury found *vis-a-vis* informed consent was that Plaintiffs had failed to carry their burden to prove the absence of informed consent. Neither Sweet nor

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[15] The Court of Appeals again misread the evidence to the disadvantage of the Plaintiffs when it implied the decedents were among "a number of patients [who] consented to the BNCT treatments." Pet. App. 7a. No evidence was cited to support this "fact."

MGH sought an instruction or a finding that Plaintiffs had affirmatively consented to the BNCT, or that they had assumed the risk of injury. The reason is obvious: There wasn't a shred of evidence to support such a finding.[16] In short, even if the jury verdict could be tortured into supporting Sweet's argument (which it cannot), the conclusion that "Sweet disclosed sufficient information to enable...an informed judgment. . . ." would be untenable, because it is unsupported by any evidence.

The instructions permitted the jury to find for Sweet on informed consent even if it found he had given the Plaintiffs no information about BNCT. The jury was instructed it should find for Sweet on the informed consent issue even if he had breached his "... duty to disclose in a reasonable manner all significant medical information...that is material to an intelligent decision by the patient...." [JA 2601]

Because the Court of Appeals denied that the transcript supported [this] reading, we cite the pertinent portion:

> If you think that informed consent wasn't obtained, then you ask yourself would [Plaintiffs] have gone forward if they had known those things which should have been known to get informed consent. If they would have gone forward anyway, the lack of informed consent makes no difference.

[JA 2605-06 (emphasis added)] The Court of Appeals apparently presumed that the trial court was alluding to a

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[16] No one testified that the Plaintiffs had been properly informed by Sweet or MGH, and there was nothing in the medical records suggesting that informed consent had been obtained. The evidence on the issue was one-sided: that Dr. Sweet overstated the potential benefits and downplayed the risks.

separate question, about proximate cause, but the jury was not asked a separate question. The informed consent verdict was general. To find for the Plaintiffs on the issue, the jury had to find both breach of the duty and injury caused thereby. Therefore, Court of Appeals erred by holding that the defense verdict on informed consent was inconsistent with the finding of negligence and by considering the alleged issue, when Defendants did not make a timely objection. Fed. R. Civ. P. 51; *see Wilson v. Bradlees of NewEngland, Inc.*, 250 F.3d 10, 21 (1st Cir. 2001).

CONCLUSION

By limiting its review to evidence received in Plaintiffs' case-in-chief, ignoring relevant evidence received thereafter, countermanding the trial judge's rulings on evidence without showing he abused his discretion, ignoring evidence proving that Defendants caused the deaths of Plaintiffs' decedents, invariably interpreting ambiguous evidence favorably to the losing party, and finding an inconsistency where none exists, the Court of Appeals nullified this Court's teachings on the standard for reviewing jury verdicts, thus effectively vitiating Plaintiffs' constitutional right to trial by jury.

The Court should grant certiorari and set this case for plenary consideration.

Respectfully submitted,

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APPENDIX

APPENDIX A

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

Nos. 00-2553, 00-2554, 00-2555

EVELYN HEINRICH, on behalf of her husband, GEORGE HEINRICH, and HENRY M. SIENKEWICZ, JR., on behalf of his mother, EILEEN ROSE SIENKEWICZ, Plaintiffs, Appellants, Cross-Appellees, ROSEMARY GUALTIERI, on behalf of her father, JOSEPH MAYNE, and WALTER CARL VAN DYKE, Representative of the Estate of WALTER CARMEN VAN DYKE, Plaintiffs, Appellants, v. ELIZABETH DUTTON SWEET and FREDERICK H. GREIN JR., Representatives of the Estate of WILLIAM H. SWEET, M.D., and MASSACHUSETTS GENERAL HOSPITAL, Defendants, Appellees, Cross-Appellants, UNITED STATES OF AMERICA, Defendant, Appellee, ESTATE OF LEE EDWARD FARR, ASSOCIATED UNIVERSITIES, INC., and MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Defendants.

August 27, 2002
OPINION

LYNCH, Circuit Judge

This is a medical malpractice case, brought in 1995, for the deaths of two Massachusetts General Hospital (MGH) patients in 1961. The plaintiffs sued the doctor and institutions responsible for treating their decedents, Eileen Sienkewicz and George Heinrich, who suffered from a terminal form of brain

cancer, with an experimental treatment known as boron neutron capture therapy (BNCT). BNCT proved not to save the lives of Sienkewicz or Heinrich.

The plaintiffs' complaint included eleven causes of action. By the time the case reached trial, there were only three causes of action left. The jury returned a verdict for the plaintiffs on two claims -- negligence and wrongful death -- and found for the defendants on the informed consent claim. The defendants appeal from the negligence and wrongful death verdicts, arguing that there was insufficient evidence.

The plaintiffs also sued the United States government under the Federal Tort Claims Act (FTCA) for its involvement in the experimental BNCT treatment through the Atomic Energy Commission (AEC). The district court determined that the government "cannot be held liable under the [FTCA] for the alleged negligence of the private defendants" and allowed the government's motion for judgment. *Heinrich v. Sweet (Heinrich IV), 83 F. Supp. 2d 214, 224 (D. Mass. 2000).* The plaintiffs appeal from that judgment and from the district court's subsequent reduction of the damages award to the plaintiffs.

We affirm the district court's judgment for the United States on the FTCA claim. We vacate the judgment for the plaintiffs on the negligence and wrongful death claims because there was insufficient evidence to meet the plaintiffs' burden of proof, and we direct entry of judgment for the defendants, Dr. Sweet and MGH.

I.

Because there is a challenge to the sufficiency of the evidence, we describe the facts in this case in the light most favorable to the verdicts. *Rodowicz v. Mass. Mut. Life Ins. Co., 279 F.3d 36, 39 (1st Cir. 2002).*

The events surrounding this case happened over four decades ago. George Heinrich and Eileen Sienkewicz, the plaintiffs'

decedents, both suffered from glioblastoma multiforme, the most common, most malignant, and deadliest form of brain cancer, and were both treated by Dr. Sweet at MGH in 1960-61. Both Heinrich and Sienkewicz consented to and participated in medical trials for Boron Neutron Capture Therapy (BNCT) performed by Dr. Sweet at a nuclear reactor facility at the Massachusetts Institute of Technology (MIT). It is these BNCT treatments that are the subject of the malpractice case.

A. Eileen Sienkewicz

Eileen Sienkewicz was admitted to MGH on June 10, 1960, complaining of severe headaches, lethargy, lack of concentration, and disorientation. At the time, she was thirty-nine years old. Dr. Sweet observed her for a few days, and then performed a left parietal-temporal craniotomy on June 13 during which he removed a mass of brain tissue which proved to be a glioblastoma multiforme, a cancerous tumor. Sienkewicz was then discharged from the hospital on June 25.

Over the summer of 1960, she suffered from lethargy, depression, insomnia, and general confusion. She was readmitted to MGH on November 13, 1960, and on November 15 she underwent BNCT, under Dr. Sweet's supervision, at the MIT reactor. At first, her lethargy worsened, but a couple of days later, she began to improve and"became more alert and began to talk again . . . and [was] essentially as responsive as she had been preoperatively." She was discharged again on December 3, 1960.

After her discharge, she continued to feel depressed. She underwent electroshock therapy at a different hospital during the first week of January 1961, her mood improved considerably, and she was "up and about doing her housework at home."

On February 27, 1961, she experienced a headache on the

left side, weakness in her right limbs, and difficulty with speech. She was again admitted to MGH and her condition improved inexplicably. She was discharged on March 4, 1961.

Over the summer of 1961, she again became disoriented and depressed. She could not sleep and she experienced nausea and severe headaches. She was readmitted to MGH on August 13, 1961, when a "[brain] scan showed a suspicious area" in the region of the tumor. She was discharged on August 19. But on September 27, she was again admitted to MGH because her condition worsened. She experienced increased headaches, speech difficulties, insomnia, and depression. At the hospital her condition only deteriorated. She was very depressed and disoriented. She eventually lapsed into a coma and died on October 31, 1961, sixteen and a half months after she was first diagnosed with brain cancer.

B. George Heinrich

George Heinrich was admitted to MGH on October 22, 1960. He complained of intermittent severe headaches, nausea, vomiting, drowsiness, and decreased vision. After Heinrich was observed for a few days, Dr. James C. White performed a left temporoparietal craniotomy on October 25 and partially removed a tumor which proved to be a glioblastoma multiforme. Heinrich was given twenty conventional radiation treatments, and his recovery seemed to be going well, but the tumor regrew and he had a second operation on December 15, 1960. Again, Heinrich's condition improved temporarily, but on January 2, 1961, he was readmitted to the hospital because his wound was infected. The infection was treated and subsided.

On January 18, 1961, Heinrich was taken to the MIT nuclear reactor and underwent BNCT. Despite the fact that Heinrich experienced some problems with his surgical wound, "for a short time he again continued to do well." But around February 10, he began to feel very lethargic and disoriented.

His condition continued to deteriorate, and a brain scan performed on April 11, 1961, showed "a definite abnormality" in the region of his tumor. By May 15, his condition had so deteriorated that he was transferred to a nursing home, where he died on May 27, 1961, about seven months after he was diagnosed with brain cancer.

C. BNCT

Boron Neutron Capture Therapy was an experimental treatment in the early 1960s for the deadliest form of brain cancer -- glioblastoma multiforme. The various estimates of the expected survival time for a patient with this type of brain cancer in 1960-61 are all measured in months.

BNCT combines chemotherapy with radiation. The theory behind BNCT at that time was that combining "boron-10 and thermal neutrons, each innocuous by itself in the doses used," would produce "a high energy nuclear reaction" that would deliver highly localized radiation to tumor cells to destroy them while largely sparing normal brain tissue. According to the theory, a compound containing boron-10 would be injected into the bloodstream supplying the brain. This compound would be taken up by tumor tissue but not by normal tissue. The tumor would then be exposed to a neutron beam produced by a nuclear reactor. When the neutron beam interacted with the boron-10, a fission reaction would occur and destroy the surrounding tumor tissue.

BNCT was first attempted at the Brookhaven National Laboratories in 1951 by a team that included Dr. Lee Edward Farr and Dr. Sweet, both neurosurgeons. BNCT was performed on ten patients from 1951-53. The experiments with BNCT at that time proved unsuccessful, and all the patients died of the brain cancer shortly after the therapy, although there was some short-lived improvement in two of the patients. Dr. Sweet and his fellow researchers stopped the experiments and tried to

learn from the failure. Three reasons for the failure of the treatment were identified: (1) the radiation dose delivered was too low; (2) the neutrons used had too low penetration; and (3) an optimal boron compound had not yet been found.

Over the next decade, Dr. Sweet and others continued to work on developing BNCT. In 1960-61 clinical trials of BNCT were again performed, this time at MIT's nuclear reactor facility. The AEC supported these trials with funding under a contract with Dr. Sweet, as well as with supplies of boron necessary to conduct the BNCT treatments. Consistent with its general policy of setting out broad objectives and leaving most decisions in the hands of the scientists and institutions who received funding for medical research, the AEC monitored the trials through written reports and occasional site visits.[1]

The team of doctors and scientists who worked with Dr. Sweet on the BNCT trials at MIT included Dr. Soloway, the principal chemist, Dr. Brownell, the principal physicist, and Dr. Ojemann, a senior resident in neurosurgery at the time. Before Dr. Sweet could proceed with the 1960-61 BNCT trials, he had to get approval from three different medical and administrative committees at MGH. In addition, he had to get the approval of the Biomedical Advisory Committee at MIT, which was comprised of representatives from MIT and three medical schools in the Boston area.

Improvements to BNCT had been made between the trials at Brookhaven and those at MIT. MIT's reactor facility was considered superior to Brookhaven's for three reasons. First, it could deliver a therapeutic dose of neutrons in less time, which was thought to be advantageous because it optimized the level of boron compound in the tumor. Second, a more optimal

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[1] While a copy of the particular contract for the MIT trials is not a part of the record, there is no indication that it differed in these respects from other AEC contracts in operation at the time.

boron-10 compound was found and used. Finally, at MIT the doctors were able to expose the tumor more directly to the neutron beam because of the placement of the equipment and the operating room.

A number of patients, all with terminal brain cancer, consented to the BNCT treatments. Sienkewicz was the first patient in this 1960-61 series of BNCT trials, while Heinrich was the sixth patient. Between their two treatments there were four other patients. The second patient was not irradiated because the tumor was too far advanced. The third patient was given the therapy and made a satisfactory recovery, but died of meningitis six weeks later. The fourth patient had recurrences of cancer in other parts of the body and died five months later. The fifth patient showed no improvement and died two months later. All in all, there were nineteen patients in this series of trials.

The doctors were very optimistic about the treatment after seeing its effect on the first patient, Sienkewicz, "who was strikingly improved" after BNCT "to the point that she could manage her own home and children until the last 2 1/2 months of her life." This improvement was known as of December 3, 1960, before Heinrich had his BNCT treatment on January 19, 1961. However, the doctors' "cheerful optimism . . . waned" when they collected the results of the entire study after its conclusion.

After the trials ended in August 1961, Dr. Sweet and other members of his team studied the results. Dr. Sweet, Dr. Ojemann, and two other doctors presented a paper at the 40th annual meeting of the American Association of Neuropathologists in 1964, summarizing the BNCT trials at MIT and analyzing the results. A revised version of the paper was later published in the Journal of Neuropathology and Experimental Neurology in 1972. In addition, Drs. Soloway, Brownell, Ojemann, and Sweet published an article in 1964 entitled "Boron-Slow Neutron Capture Therapy: Present

Status." Sweet and his coauthors concluded that the BNCT trials at MIT failed due to four main "deficiencies," including:

> 1) [Their] lack of appreciation of the full complexity and requirements of our biological systems with regard to the boron compound, specifically to the need to clear it from the cerebral blood stream.
> 2) The inadequacy of the current status of knowledge regarding boron chemistry.
> 3) Insufficient information as to the methods of optimizing the shape of neutron beam for capture therapy.
> 4) The lack of the requisite dosimetric [measuring] equipment.

They also stated that "the theoretical aspects which prompted [their] initial attempts" remained "attractive," and expressed optimism that, after further study in a variety of scientific fields, "[their] therapeutic goal may be within reach." Since the 1960-61 BNCT trials at MIT, there have been further BNCT trials in other places by other doctors. Most notably, Dr. Hiroshi Hatanaka performed clinical trials in Japan between 1968 and 1989 and achieved a survival rate of up to five years in some of his patients.[2]

The medical doctors most closely involved with the BNCT trials could not, by reason of age and infirmity or death, testify at the belated trial. Dr. Farr, who supervised the BNCT trials at Brookhaven, died in 1997. Dr. Sweet died after the trial in January 2001. He did not testify at trial because his age and medical condition had by then rendered him incompetent.

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[2] The defendants offered additional evidence of ongoing work with BNCT, but the district court excluded that evidence.

II.

The procedural history of this case is complicated. The plaintiffs first brought the case in the Eastern District of New York on September 21, 1995, as a putative class action on behalf of their decedents. The case was transferred to the District of Massachusetts on August 20, 1997. The complaint, filed on behalf of decedents from the BNCT trials both at Brookhaven in 1951-53 and MIT in 1960-61, included eleven causes of action against all of the parties involved in the BNCT trials: Dr. Sweet; MGH; MIT; Associated Universities, Inc., which operated Brookhaven National Laboratories; the Estate of Dr. Lee Edward Farr, who supervised the BNCT trials at Brookhaven; and the United States government, which was responsible for the AEC.

On April 20, 1999, the district court denied the government's motion to dismiss the FTCA claims on the basis of the statute of limitations. *Heinrich v. Sweet (Heinrich I), 44 F. Supp. 2d 408 (D. Mass. 1999).*

On April 30, 1999, the district court dismissed plaintiffs' battery, intentional infliction of emotional distress, strict liability, toxic substances, and crimes against humanity claims. *Heinrich v. Sweet (Heinrich II), 49 F. Supp. 2d 27 (D. Mass. 1999).*

On August 16, 1999, the district court dismissed the state law claims of plaintiffs whose decedents underwent BNCT at the Brookhaven National Laboratories in New York (Joseph Mayne and Walter Carmen Van Dyke) as untimely under New York law. *Heinrich v. Sweet (Heinrich III), 62 F. Supp. 2d 282 (D. Mass. 1999).* At the same time, the district court held that the FTCA's independent contractor exception and discretionary function exception did not apply to the case and declined to dismiss plaintiffs' FTCA claims against the United States on either basis. *Id. at 321-26.* On September 9, 1999, the district

court granted summary judgment against the plaintiffs' claims brought under the doctrine of *Bivens v. Six Unklnown Named Agents of the Federal Bureau of Narcotics, 403 U.S. 388 (1971).*[3]

The jury heard evidence over fifteen days between September 10 and October 7, 1999. At the end of the trial, the court dismissed the fraud and negligent misrepresentation claims on a motion for judgment as a matter of law.

Finally, the jury returned a verdict for defendant MIT on all counts. The jury's verdict form had verdicts for Dr. Sweet and MGH on the same line, as if they were one party, because the plaintiffs' theory of liability as to MGH was based exclusively on vicarious liability for Dr. Sweet's actions. The jury returned a verdict for defendants Dr. Sweet and MGH on the informed consent count, and for plaintiffs Heinrich and Sienkewicz on the negligence and wrongful death counts. The jury assessed a total of $ 3 million in compensatory damages against MGH and Dr. Sweet jointly and severally. The jury also assessed $ 1.75 million in punitive damages against Dr. Sweet, and $ 3.25 million against MGH.[4]

Because FTCA claims are heard by a judge rather than a jury, see *28 U.S.C. § 2402,* the district court ruled separately on the remaining claims against the federal government on February 9, 2000. *Heinrich v. Sweet (Heinrich IV), 83 F. Supp. 2d 214 (D. Mass. 2000).* Based on further evidence made available in post- trial proceedings about the AEC's

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[3] The district court made other rulings permitting plaintiffs' claims to survive the statute of limitations and retroactivity defenses, and ruled for plaintiffs on issues of which statutory scheme applied. *Heinrich III, 62 F. Supp. 2d at 304.* We have no occasion to pass on whether these rulings were correct.

[4] After the trial, on January 5, 2000, the district court denied class certification.

involvement in the BNCT treatments, the court reversed its previous determination, found that the independent contractor exception applied, and ordered judgment for the United States. *Id. at 221-24.* Because its finding on the independent contractor exception disposed of the FTCA claims, the district court deemed it unnecessary to reach the issue of the discretionary function exception.

Dr. Sweet and MGH filed a motion for a new trial, a renewed motion for judgment as a matter of law, and a motion for reduction of the jury award. Among the grounds asserted in their motion for judgment as a matter of law was that the evidence did not meet the plaintiffs' burden of proof. The district court rejected the motion for a new trial and the motion for judgment as a matter of law. The district court ruled from the bench that "the evidence is sufficient to support each of the causes of action which were submitted to the jury" but gave no reasons for its ruling. In a written opinion, the district court reduced the jury award because it determined that the jury had been instructed to apply the incorrect Massachusetts wrongful death statute (the 1995 statute instead of the one in effect when the treatments took place). Thus, the award was reduced to $ 750,000 (joint and several) for the negligence count, and $ 20,000 from each defendant to each plaintiff for the wrongful death count. Heinrich v. Sweet (Heinrich V), *118 F. Supp. 2d 73, 77-83 (D. Mass. 2000).*

III.

The plaintiffs and the defendants appeal from the judgments of the district court. Plaintiffs argue that the jury award for the wrongful death claims should not have been reduced, that they should be awarded prejudgment interest, and that the judgment for the United States on the FTCA claim should be reversed.

Defendants MGH and Dr. Sweet argue that judgment should have been entered in their favor as a matter of law

because the statute of limitations on the plaintiffs' claims had run. In addition, they argue that there was insufficient evidence to support the negligence and wrongful death claims. They argue that the plaintiffs did not show that Dr. Sweet departed from the applicable standard of care or that his actions hastened the decedents' deaths. MGH also argues that it cannot be held liable in light of the state charitable immunity doctrine. The government argues that it cannot be held liable under the FTCA since both the independent contractor exception and the discretionary function exception under that Act apply. The government also asserts that the FTCA's statute of limitations bars plaintiffs' claims against the United States.

Because we agree with the defendants that there was insufficient evidence to support the negligence and wrongful death claims, we do not reach the plaintiffs' arguments about the reduction of the jury award and prejudgment interest. We also do not reach the statute of limitations issues or MGH's charitable immunity argument.

IV.

A. Federal Tort Claims Act

Before proceeding to the underlying negligence and wrongful death claims, we consider whether the FTCA, *28 U.S.C. § § 1346*(b), 2671-80 (2000), waives sovereign immunity so that the United States is susceptible to liability for these causes of action, whatever their merits. We affirm the district court's judgment for the United States.

The district court concluded that the relationship that the AEC had with Dr. Sweet and MGH was an independent contractor relationship, because the AEC did not exercise "detailed supervision or day-to-day control" over the BNCT treatments. *Heinrich IV, 83 F. Supp. 2d at 221-24.* This finding required dismissal of the claims under the independent contractor exception to the FTCA, *28 U.S.C. § 2671.* See *United States v. Orleans, 425 U.S. 807, 816-17, 48 L. Ed. 2d*

390, 96 S. Ct. 1971 (1976). Rather than directly disputing the district court's characterization of the relationship, plaintiffs object that "the U.S. should be liable for the AEC's failure to follow its policy on human radiation experiments." As plaintiffs summarize it, this policy required a "reasonable basis to believe the experiment would provide therapeutic benefit to the patient."

This argument is unavailing. Plaintiffs derive the purported "policy" from four letters written by AEC officials in 1947 and 1951, none of them about BNCT itself. There is, however, no clear evidence that these letters represented any specific or binding AEC policy. They are individual communications, not necessarily disseminated to anyone but their individual addressees. They contain only broadly-worded statements to the effect that a doctor should not conduct experimental treatments without a "reasonable hope" or an "expectation" of therapeutic benefit. One of the 1947 letters also emphasized the AEC's "understanding" that "the decision as to the advisability of the treatment will be made by the doctor concerned." The final report of the presidentially-appointed Advisory Committee on Human Radiation Experiments, introduced into evidence by plaintiffs, analyzed the same correspondence and concluded that it did not clearly represent formal policy, with the possible exception of informed consent requirements not at issue here.

Furthermore, even if the letters stated the AEC's policy, that policy would not restrict the AEC's discretion concerning BNCT treatments. The FTCA shields from liability a federal agency's exercise of a "discretionary function." *28 U.S.C. § 2680*(a). The plaintiffs' asserted policy requiring a "reasonable basis" to expect "therapeutic benefit" would hardly constrain the AEC's judgment at all. It would be quite different from the narrow, discretion-limiting rule in the case on which plaintiffs rely so heavily, *Berkovitz v. United States, 486 U.S. 531, 100 L. Ed. 2d 531, 108 S. Ct. 1954 (1988),* which concerned the

detailed regulatory scheme for licensing and testing of polio vaccines. Rather, these broad parameters leave a host of case-by-case judgments for agency officials to make, each requiring the exercise of discretion and the consideration of the agency's overarching policy goals. This is a classic discretionary function. See *United States v. Gaubert, 499 U.S. 315, 327-34, 113 L. Ed. 2d 335, 111 S. Ct. 1267 (1991)* (regulators' choices in oversight of savings and loan qualify as discretionary function); *Shansky v. United States, 164 F.3d 688, 691 (1st Cir. 1999)* (general statement in agency operating manual leaves discretion to individual managers); *Irving v. United States, 162 F.3d 154, 162-63 (1st Cir. 1998)* (en banc) (guidelines in OSHA inspection manual leave discretion to individual inspectors).

We affirm the district court's holding that the FTCA does not permit suit against the federal government.

B. Sufficiency of the Evidence Against Dr. Sweet and MGH

Defendants Dr. Sweet and MGH challenge the sufficiency of the evidence against them on the negligence and wrongful death claims and argue that the district court should have entered judgment as a matter of law in their favor. The district court, ruling from the bench, denied the motion for judgment as a matter of law based on insufficiency of the evidence without stating its reasons for doing so. We review de novo a district court's denial of a Rule 50 motion for judgment as a matter of law. But "our review is weighted toward preservation of the jury verdict," *Rodowicz, 279 F.3d at 41,* and "we must affirm unless the evidence was 'so strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them," *Walton v. Nalco Chem. Co., 272 F.3d 13, 23 (1st Cir. 2001)* (quoting *Negron v. Caleb Brett U.S.A., Inc., 212 F.3d 666, 668 (1st Cir. 2000)).*

Massachusetts law governs both the wrongful death and negligence claims.

1. Wrongful Death

Dr. Sweet and MGH argue that because there was no evidence that BNCT hastened the death of either decedent, the district court should have entered judgment as a matter of law in the defendants' favor on the wrongful death claim, and the jury verdict against them on this claim should be vacated.

The district court instructed the jury that in order for the plaintiffs to receive compensatory damages for a wrongful death claim, the defendant had "to shorten the life" of the decedent.[5] The court explained that "if, had there been no . . . procedure, the person would have gone downhill, and would eventually then have died of the disease, but because of the procedure they died earlier, then you can award damages." The plaintiffs did not object to this instruction specifically at the time it was given, and so they have forfeited any potential objection to it on appeal, absent plain error. See Fed. R. Civ. P. 51; *Gray v. Genlyte Group, 289 F.3d 128, 133-34 (1st Cir. 2002).*

This instruction was not inconsistent with Massachusetts case law.[6] To make out a claim for wrongful death on a negligence theory, a plaintiff must show that the defendant's negligence caused the plaintiff to die prematurely. *Harlow v. Chin, 405 Mass. 697, 545 N.E.2d 602, 605 (1989)* ("A plaintiff

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[5] Plaintiffs based their wrongful death claim on both negligence and intentional misconduct. Cf. *Necktas v. Gen. Motors Corp., 357 Mass. 546, 259 N.E.2d 234, 236 (1970)* ("The right of recovery for death . . . is based either upon negligence or upon a wilful, wanton or reckless act causing death."). The instructions to the jury about wrongful death focused solely on wrongful death as a negligence claim, and we do not understand plaintiffs to pursue an intentional misconduct claim on appeal.

[6] Because of this jury instruction, issued without objection, we need not reach the issue of whether there are other methods to win compensatory damages for wrongful death under Massachusetts law.

in a medical malpractice action has the burden of proving that the physician's negligence was the proximate cause of the plaintiff's injuries."). Defendants dispute their liability for wrongful death by focusing on this causation element. Under these jury instructions, where the plaintiffs were terminally ill and death was imminent, plaintiffs must show that the defendant's actions hastened death "even though it would have occurred at no very remote date from other causes." *Edwards v. Warwick, 317 Mass. 573, 59 N.E.2d 194, 196 (1945);* see also *Coburn v. Moore, 320 Mass. 116, 68 N.E.2d 5, 10 (1946)* (holding that there was "enough to show a causal relation between the negligence of the defendant and the death of the intestate" where the defendant's actions "accelerated [intestate's] death"); *Walker v. Gage, 223 Mass. 179, 111 N.E. 766, 767 (1916)*(holding that evidence that the accident hastened intestate's death was "enough legally to constitute the accident the proximate cause of his death"). There was not plain error in the instruction that plaintiffs must show that the defendants "shortened the life" of the decedent.

The necessary "causal connection between the negligence of the defendant, if found, and the plaintiff's injuries . . . is a question that a jury could determine only with the aid of expert opinion." *Berardi v. Menicks, 340 Mass. 396, 164 N.E.2d 544, 547 (1960);* see also *Mitchell v. United States, 141 F.3d 8, 13 (1st Cir. 1998); Harlow, 545 N.E.2d at 605.* Plaintiffs argue that the jury's finding that death was hastened by defendant's negligence need not be based on expert testimony if there is any probative evidence at all. Plaintiffs rely on *Edwards, 59 N.E.2d at 195-96,* where the court permitted consideration of the issue of whether an automobile accident had hastened death. Edwards is inapposite. Contrary to plaintiffs' argument, there was expert medical testimony in Edwards tying the death to the auto accident. Furthermore, in a medical malpractice case in which plaintiff argues that the treatment, not the terminal disease, hastened the death, and all of the expert testimony is

that it cannot be said that the treatment hastened the death, a jury is not free to reach a contrary conclusion. Whether such a treatment ultimately hastened a patient's death is not a topic of common experience; it requires expert testimony.[7] There is no evidence at all in the record that BNCT hastened decedents' deaths.

Plaintiffs' own medical expert, Dr. Larry Junck, a professor of neurology and neuro-oncology, plainly stated that he could not say that BNCT hastened the decedents' deaths:

> I think it would be very difficult for me to say what would have happened had they not received that treatment. That would be just hypothetical and it's just the kind of thing that I would have no basis for saying what would have happened had they not received BNCT and perhaps received some other treatment.

In addition, Dr. Junck responded on cross-examination as follows:

> Q. But you certainly cannot say that the administration of BNCT in any way hastened [Sienkewicz's] death?
> A. That's correct.
> Q. And as to George Heinrich you cannot say that the administration of the BNCT in any way hastened George Heinrich's death; is that correct?
> A. That's correct.

Dr. Junck testified that in the early 1960s the median life

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[7] Plaintiffs also argue that such proof may come in documentary form; but the documents they cite do not support their proposition.

expectancy for glioblastoma multiforme patients such as Sienkewicz and Heinrich, from diagnosis to death, without any treatment, was four to six months. He also testified that the life expectancy for a glioblastoma multiforme patient who underwent conventional therapy including conventional radiation was eight to twelve months. Sienkewicz well exceeded this life expectancy as she lived for sixteen and a half months after she was first diagnosed, and eleven months after she underwent BNCT. Heinrich survived for seven months after he was first diagnosed. Although this is slightly below the median life expectancy for glioblastoma multiforme patients who received conventional therapy, as identified by Dr. Junck, it is not sufficiently below the median to show that Heinrich would have lived longer had he not received BNCT.

In addition, two of defendants' experts also clearly testified that they could not determine that BNCT hastened the decedents' deaths. Dr. Raymond Laws, a professor of neurosurgery and a practicing neurosurgeon, stated that he "found no evidence that the BNCT hastened [Sienkewicz's] demise" or that "[it] hastened [Heinrich's] demise." Dr. Edward G. Koski, an anesthesiologist and Director of Human Research Affairs for Partners Health Care Systems, which includes MGH, stated that "Ms. Sienkewicz appeared to have lived somewhat longer than would have been expected given the nature of her tumor and the usual course of the disease and people in her age group."

In response, plaintiffs attempt to rely on an article entitled "The Longevity of Patients with Glioblastoma Multiforme," published in 1950 in the Journal of Neurosurgery. The article stated that "the average duration from the first symptom to exitus was 17 months." The plaintiffs depend on this assertion to say that both Sienkewicz and Heinrich lived below the life expectancy and that BNCT hastened their deaths. The very next two sentences in this article read: "However, this average was distorted by the unusual cases to be discussed. The median

survival was 8.3 months, a figure that is more indicative of the usual case." Moreover, when Dr. Junck, plaintiffs' expert, himself commented on this portion of the article, he said "the average really isn't telling us as much about what the typical patient did because it's so heavily influenced by two particular people. The median is a figure that describes the patient in the exact middle of the group."

The plaintiffs also rely on the fact that "Dr[]. Sweet . . . as well as other writers . . . concluded that there is no evidence that the BNCT experiments at the MIT reactor in 1960 and 1961 prolonged anyone's life." In an article written by Dr. Sweet and others, published in the Journal of Neuropathology and Experimental Neurology in 1972, the authors stated that BNCT, as utilized in 1961, "offered no advantage over standard methods of therapy already available." Similarly, in an article by Dr. Sweet and others about the "present status" of BNCT, published in 1964, the authors wrote that there was "only one instance of prolonged improvement," apparently referring to Sienkewicz. There is no doubt that these articles, written by the doctors most closely involved with BNCT, stated that BNCT as performed in 1961 was not a more successful way to treat glioblastoma multiforme than the conventional treatment available at the time. However, the articles also say nothing about BNCT causing the death of the patients earlier than would otherwise be expected. In fact, in the article published in 1972, the authors say that "the average survival time from the time of diagnosis . . . was roughly the same [as the] average survival for a similar large series treated [in the conventional manner.]"

Taking the evidence in the light most favorable to the verdict, there was no evidence that BNCT hastened the death of Heinrich or Sienkewicz. The evidence was overwhelmingly inconsistent with the verdicts for plaintiffs on their wrongful death claims and is therefore insufficient to uphold those verdicts. Independently, our conclusion that the evidence was

not sufficient to support a verdict of negligence, described below, also means that the wrongful death verdict cannot stand.

2. Negligence

Dr. Sweet and MGH challenge the jury's verdict in favor of plaintiffs on the negligence claims. They argue that there was insufficient evidence to show that Dr. Sweet deviated from the applicable standard of care.

To prevail on a negligence claim, a plaintiff must show by a preponderance of the evidence "(1) a legal duty owed by defendant to plaintiff; (2) a breach of that duty; (3) proximate or legal cause; and (4) actual damage or injury." *Jorgensen v. Mass. Port Auth., 905 F.2d 515, 522 (1st Cir. 1990);* see also *Harlow, 545 N.E.2d at 604-05* ("'To entitle the plaintiff to go to the jury [on a negligence claim] there must be sufficient evidence to warrant a finding (1) of negligence on the defendant's part, and (2) of a causal relationship between the negligence and the plaintiff's injuries.'" (quoting *Civitarese v. Gorney, 358 Mass. 652, 266 N.E.2d 668, 671 (1971))).*

The defendants argue that there was insufficient evidence at trial to show that Dr. Sweet violated his duty of care to the plaintiffs' decedents by failing to comply with the applicable standard of care.

The Massachusetts Supreme Judicial Court articulated the standard of care for physicians in Brune v. Belinkoff:

The proper standard is whether the physician, if a general practitioner, has exercised the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession. In applying this standard it is permissible to consider the medical resources available to the physician as one circumstance in determining the skill and care required. Under this standard some allowance is thus made for the type of community in which the physician carries on his practice.

> One holding himself out as a specialist should be held to the standard of care and skill of the average member of the profession practising the specialty, taking into account the advances in the profession. And, as in the case of the general practitioner, it is permissible to consider the medical resources available to him.

354 Mass. 102, 235 N.E.2d 793, 798 (1968) (emphasis added) (citations omitted); see also *Stepakoff v. Kantar, 393 Mass. 836, 473 N.E.2d 1131, 1135 (1985).* The standard of care for medical doctors is not static or rigid. It is a standard that changes depending on many factors, including a doctor's specialty, the resources available, and the advances of the medical profession at the time of the alleged negligent act. The duty to be measured is the one as of the time of the act. Here, that means November 1960 as to Sienkewicz, and January 1961 as to Heinrich.

In this case, the determination of the standard of care owed by Dr. Sweet to the decedents must be influenced by his specialty, the state of medical practice and advances as of November 1960 and January 1961, and the fact that in treating the decedents he was also conducting medical research for a new treatment. Under the circumstances of this case, where the jury was asked to evaluate the doctor's conduct many years after the events took place, it is especially important that the correct standard of care in place at the time of the treatments be clearly established and used.

Massachusetts law requires that unless "'the negligence and harmful results are sufficiently obvious as to lie within common knowledge,'" such as "a case where there is certainty of a foreign object or dangerous physical organ left in a patient during an operation," the plaintiff must present expert testimony as to the standard of care and its breach. *Haggerty v. McCarthy, 344 Mass. 136, 181 N.E.2d 562, 565-66 (1962)* (quoting *Cyr v. Giesen, 150 Me. 248, 108 A.2d 316, 318*

(1954)); see also *Collins v. Baron, 392 Mass. 565, 467 N.E.2d 171, 173-74 (1984)*. This case required such expert testimony. As an alternative or an addition to expert testimony, the plaintiff may also present admissions from the defendant about his fault. *Collins, 467 N.E.2d at 173-74.* "Testimony concerning conclusory admissions by a malpractice defendant may suffice to sustain a jury's finding of negligence if, from the admission, the jury 'could infer an acknowledgment of all the necessary elements of legal liability.'" Id. (quoting *Zimmerman v. Litvich, 297 Mass. 91, 7 N.E.2d 437, 438 (1937))*.

Plaintiffs' theory of the case, presented in their closing argument, was that Dr. Sweet knew all along that BNCT had no therapeutic value and that it would harm his patients, but that he nonetheless proceeded with the BNCT trials in the name of the progress of medical research and concealed what he knew about the danger of BNCT from his patients.

Plaintiffs make a several-pronged argument. The first is that before Dr. Sweet used BNCT in treating Heinrich and Sienkewicz, Dr. Sweet had no basis to believe that BNCT would be therapeutic. More specifically, they maintain that Dr. Sweet did not know how much radiation he would give and whether it would help his patients or lead to their deaths. Plaintiffs' theory was that in 1960-61 the defendants should not have proceeded with BNCT when they had not found a boron compound of acceptable toxicity and had not established a way of determining the level of radiation that was going to the tumor as opposed to normal brain tissue.[8] Plaintiffs also assert that Dr. Sweet knew after he used BNCT on the two patients and before their deaths that BNCT caused substantial loss of

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[8] No evidence was ever submitted that there was any way of achieving greater clarity about these points other than through human subjects. The evidence in the record is that animal studies were not sufficiently similar.

function and brain necrosis; the record contains no evidence to show these final assertions.

Plaintiffs presented two medical expert witnesses to support their theory of the case: Dr. Junck, a professor of neurology and neuro-oncology, and Dr. Grodin, an expert on medical ethics. For purposes of this appeal, we assume that the district court did not abuse its discretion in qualifying any of the medical experts to testify, including Dr. Junck and Dr. Grodin.

Plaintiffs' lead expert, Dr. Junck, was not asked to relate his opinion as to whether Dr. Sweet had violated the relevant standard of care. Instead, he was asked, over objection, whether Dr. Sweet, MGH, and MIT had acted "appropriately or inappropriately, responsibly or irresponsibly, in performing human experiments on George Heinrich and Eileen Sienkewicz." In response, Dr. Junck said: "I believe that the evidence indicated that Massachusetts General Hospital and MIT acted inappropriately in relation to performing human experiments on the two persons named." In response to a follow-up question, again allowed over objection, Dr. Junck extended this statement to include Dr. Sweet.

There are several problems with the expert testimony presented by Dr. Junck, plaintiffs' lead expert. The first two concerns are related. First, we think the question put to Dr. Junck was wrong. Its highly suggestive emphasis on acting "responsibly" and its prejudicial reference to "human experimentation" did not concern a standard of care for medical treatment. Second, the form of the question was incorrect and did not lead to the required information. While the standard of care question need not be formulaic and some leeway is allowed, see *Bradford v. Baystate Med. Ctr., 415 Mass. 202, 613 N.E.2d 82, 86-87 & n.6 (1993); Nickerson v. Lee, 42 Mass. App. Ct. 106, 674 N.E.2d 1111, 1115 (1997); Rahilly v. North Adams Reg'l Hosp., 36 Mass. App. Ct. 714, 636 N.E.2d 280, 283 n.6 (1994)*, we think this question was inadequate to tie Dr. Junck's opinion to the standard of care for a specialist like Dr.

Sweet in 1960-61. To say that Dr. Sweet was in breach of the standard of care, the jury must know what the standard of care was, see 37 J.R. Nolan & L.J. Sartorio, Massachusetts Practice § 279, at 452 (2d ed. 1989), and neither the question presented to Dr. Junck nor his answer provide this information.

Apart from the incorrect form of the question presented to Dr. Junck, there is a fundamental problem with his opinion: it was based in an undifferentiated fashion on information, analyses, and publications which became available only after the BNCT treatments had been undertaken and not on the information that was available to Dr. Sweet when he conducted the trials. Dr. Junck relied on articles written about the BNCT trials conducted at MIT after the trials ended (and after Heinrich and Sienkewicz had died). Such articles may sometimes contain probative information about the doctors' state of knowledge before they begin a set a medical trials. This is not the case here. Instead, the articles' pertinent information was learned after the trials, once the doctors had an opportunity to study and analyze them. For example, in March 1962, Dr. Sweet wrote a report to the AEC in which he stated that BNCT destroyed too much normal brain tissue along with the tumor. This report was written with the benefit of hindsight, and does not show what Dr. Sweet and his team knew when they were conducting the trials in 1960-61. Much less does it support the conclusion that Dr. Sweet violated any standard of care in 1960-61. The report is not an admission of negligence. That medical research at times produces results less than hoped for is to be expected. This does not logically lead to the conclusion that the research should not be undertaken. To the extent that Dr. Junck described this report as evidence on which he relied in forming his opinion, it was not evidence about what Dr. Sweet knew at the time of the trials, but about what he learned as a result of the trials.

Furthermore, some of Dr. Junck's opinions rested on particular data or publications that do not support his

conclusions and have been mischaracterized by plaintiffs in their briefs to us. We give some examples. In testifying that no acceptable boron compound had been found by the time of the BNCT trials at MIT, Dr. Junck relied on a document in which an AEC representative memorialized his March 30, 1959, meeting with Drs. Sweet, Brownell, and Soloway. The memorandum includes a paragraph about the doctors' discussion of the "brain tumor therapy" research and notes that one of "the major issues at stake" was "the finding of a suitable boron compound which has a low toxicity." However, the document goes on to note that "Dr. Soloway, the biochemist . . . [said] he had received a very promising compound from [another doctor]. . . ." This document is insufficient to show that Dr. Sweet's team's research was so inadequate as to violate the standard of care by the time the BNCT trials took place.[9]

To support his view that Dr. Sweet knew nothing about determining the level of radiation which was going to the tumor as opposed to normal brain tissue, Dr. Junck relied on a letter dated January 31, 1952, written from the Brookhaven National Laboratories to Dr. Sweet's office. The letter stated that the levels of radiation that patients had received were not actually known because of the difficulties of measuring them during the treatment. This letter was written while the earlier BNCT trials were taking place at Brookhaven in the early 1950s and seems to relate information about those trials. The letter was relevant, but insufficient to establish that Dr. Sweet knew so little at the time he conducted the BNCT trials at MIT in 1960-61 as to violate the standard of care.

In turn, the testimony of Dr. Grodin, the plaintiffs' medical ethics expert, about BNCT was that there was no evidence that

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[9] Plaintiffs also point to a portion of Dr. Junck's testimony in which he said "they hadn't . . . found a boron compound . . . that was free of a lot of substantial side effects." But this testimony was struck from the record and its citation to us is improper.

there was any benefit, potential benefit to the individual terminally ill subjects and there was significant evidence of harm, cell death due to necrosis, and therefore it was [his] opinion that in weighing the risks against the benefits that the risks outweighed the benefits and therefore . . . the research should not be conducted.

Dr. Grodin's conclusion suffers from the same problems as Dr. Junck's conclusion -- it was not tied to the time period in question,[10] it did not state the standard of care or that Sweet had

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[10] In fact, the totality of the pertinent testimony leading up to the Grodin testimony quoted in the text was as follows:

> Q: Did you reach a conclusion as to whether or not those boron injection experiments had a favorable risk/benefit ratio at the time they were conducted in the period 1960 to 1962?...
> Opposing Counsel: Same objection.
>
> The Court: Noted but overruled. He may answer.
>
> A: That insofar as there was no therapeutic benefit to the boron injection in these terminally ill patients and there was some toxic potential for the voron compound that the risk outweighed the benefits.
> O: All right. And did you do a similar risk/benefit analysis with regard to the BNCT experiments?
> A: Yes, I did.
>
> Q: And what conclusion did you reach to a reasonable degree of medical certainty with regard to the BNCT experiments?
> Opposing Counel: Objection.
>
> The Court: Overruled.

Among the other problems with his testimony is that Dr. Grodin's opinion about the boron injection was tied to the 1960-61 time period when the BNCT trials were conducted at MIT, but not his opinion about

violated the standard of care and it depended heavily on information about BNCT that became available to Dr. Sweet and his team only after the completion and analysis of the trials. In addition, the evidence does not support Dr. Grodin's conclusion that the BNCT trials should not have been approved.

Dr. Grodin's opinion was based, in part, on a paper presented by Dr. Sweet and others to the American Association of Neuropathologists in 1964, after the events in question and learning from those events. The paper stated that "the cause of death at post mortem examination was cerebral in nature, specifically extensive radiation necrosis to the brain in nine [of fourteen subjects]." Of course, after-the-fact autopsy evidence does not establish what the state of knowledge was at the time of treatment. To the extent that Dr. Grodin relied on this evidence in forming his opinion, his reliance was misplaced. Again, this was not evidence about what Dr. Sweet knew at the time of the trials, but about what he learned as a result of the trials.

In addition, Dr. Grodin's opinion in essence was that the research project should not have been approved. However, he was unaware of the scope of the duties of the various medical committees which reviewed and approved the BNCT research in 1960- 61, he was unaware of what materials were before the MIT committee which approved the BNCT trials, and he had no basis to say the committee did not act in good faith. There was not an adequate foundation established for Dr. Grodin to express an opinion that the treatments, approved at the time by numerous relevant committees, violated the standard of care in 1960-61.

Besides the expert testimony, plaintiffs also rely on several

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the BNCT experiments.

documents admitted into evidence to support that testimony and their theory that Dr. Sweet knew before he conducted the BNCT trials at MIT that they would have no therapeutic value. This claim by plaintiffs is undercut by the fact that Sienkewicz's condition improved dramatically after BNCT, and that this instilled confidence and optimism in Dr. Sweet and his team in the treatment. There were only a few pieces of documentary evidence that contained information on the knowledge about BNCT before 1960-61. None of them show that Dr. Sweet knew before he conducted the BNCT trials that they would have no therapeutic value.

First, there was a 1951 letter from the AEC to Dr. Sweet asking him for more information about BNCT before supplying him with boron 10. The letter asked Dr. Sweet whether BNCT trials had been conducted on animals, and what the dosage of radiation would be. Dr. Sweet responded with his own letter stating that no experiments had been performed on animals because these would not be useful "since the conditions are so different," and that there were no "useful answers" to any of the questions. On its face this is not evidence of negligence. It is also evidence from a decade before the trials in question took place.[11]

Second, there was a 1955 article by Dr. Sweet and others published in Cancer that analyzed the results of autopsies of eight BNCT patients at Brookhaven in 1951-52. The article noted that the patients' brains were adversely affected by radiation which may have been caused by BNCT. However, the article was written about the BNCT trials at Brookhaven, which

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[11] There was also the 1952 letter from Brookhaven to Dr. Sweet's office at MGH, discussed previously with regard to Dr. Junck's testimony. Again, this letter, discussing the lack of knowledge about the amount of radiation that patients received during BNCT, pertained to the BNCT studies at Brookhaven and does not say much about the knowledge accumulated by Dr. Sweet and his team almost a decade later.

occurred nearly a decade before the BNCT studies in question here. In addition, the evidence at trial was that the MIT facility was superior to the Brookhaven facility and was designed in ways that were meant to address these concerns.

Third, there were two 1959 memoranda by an AEC representative which memorialized his meetings with Dr. Sweet and some members of Dr. Sweet's team. Although the first memorandum, discussed earlier, stated a remaining problem with BNCT, it was also optimistic that a solution to the problem was near. Similarly, the second memorandum of a June 19, 1959, meeting stated that Dr. Sweet had "some rough going" with the BNCT research, but again expressed optimism about the contacts made by Dr. Soloway and how these would help him find a suitable boron compound.

Lastly, there were two articles written in 1954 by Dr. Sweet and others in which the BNCT trials at Brookhaven were analyzed. These articles pointed to the problems with BNCT at the time, but also expressed hope about the further use of BNCT after more exploration and research. They do not support the conclusion that there was no evidence of any potential benefit to the patients from BNCT in 1960-61.

The plaintiffs also rely on articles and documents written by Dr. Sweet and others on his team after the BNCT trials conducted at MIT, to support the contention that the doctors themselves admitted to wrongdoing, and that these alleged admissions are sufficient to show that Dr. Sweet violated his duty of care to the plaintiffs. For example, in 1964 Dr. Sweet co- authored an article entitled "Boron-Slow Neutron Capture Therapy: Present Status," in which the authors concluded that there were four main "deficiencies" that rendered BNCT not "practicable," and went on to outline those deficiencies. No reasonable reader could view the articles, written after the BNCT trials at MIT ended, based on hindsight, and presented to colleagues in science and medicine for consideration, as admissions of wrongdoing. The articles, rather, are objective

academic appraisals of the BNCT trials and their failures. The purpose of medical research and trials is to learn from them and improve medical treatments for diseases, including treatment for the subjects of the trials. There would surely be a chilling effect on research in the medical field and deterrence of important progress in medical treatments if doctors and scientists could not frankly assess the successes and failures of their studies in published academic articles so that others can build on their work and learn from it.

The only correct articulation at trial of the standard of care applicable to Dr. Sweet came from one of the defense experts, Dr. Charles Fager, a neurosurgeon. In response to questions asking him to "take into consideration the advances in the profession at the time and the resources available to Dr. Sweet at that time . . . for a person practicing within the specialty of neurosurgery at that time," he testified that he had an opinion, given those factors. Within those criteria, which were not the criteria used by plaintiffs' experts, Dr. Fager stated that "Dr. Sweet certainly maintained the acceptable methods of practice of neurosurgery at that time."

Dr. Fager formed his opinion by considering what was known about glioblastoma multiforme and BNCT and its effects in 1960-61, when Dr. Sweet conducted the trials in question. More specifically, he took into account the circumstances surrounding the plaintiffs' BNCT treatments. He stated that Sienkewicz was suffering from a "malignant brain tumor," and that there was a "recurrence of tumor" after Dr. Sweet operated on her. He also said that Heinrich was suffering from "a malignant invasive tumor" and that "he had no hope of survival."

Dr. Koski, the Director of Human Research Affairs for Partners Health Care System (which includes MGH) also provided expert testimony for the defendants. As Director of Human Research Affairs, Dr. Koski has "broad responsibility for oversight of all human investigation that is conducted

within the Partners Health Care System, particularly with respect to protection of human subjects who are participating in research . . . ." Dr. Koski testified that various committees at MGH had reviewed and approved Dr. Sweet's application to conduct the BNCT trials at MIT, including the surgical executive committee, which "considered issues of treatments and therapies that came up before the [surgery] department"; the general executive committee of the staff, which "is the principal governing committee of the Massachusetts General Hospital"; and the Board of Trustees, which has "the overall responsibility for governance of the hospital." Thus, Dr. Sweet's proposal to conduct BNCT trials in 1960-61 received three levels of administrative review at MGH, and was approved at every level. Furthermore, other evidence indicated that the BNCT trials were also reviewed and approved by the Biomedical Advisory Committee at MIT, which was comprised of representatives from MIT and three area medical schools and whose function was "the review and approval of biomedical experiments . . . at the reactor from the point of view of provision of maximum safety to investigators, patients, or any human beings on whom tracer experiments, diagnosis, or therapy is to be performed." The ten members of the MIT committee -- seven from institutions other than MIT -- had to be unanimous on their vote to approve a research project. Approval by these various committees is very compelling evidence to show that the BNCT trials complied with the prevalent standard of care at the time. Indeed, Dr. Koski stated that "in [his] opinion, the initiation of the boron neutron capture therapy studies [was] in accordance with the process that was prevailing at the time."

Our discussion above is alone sufficient to vacate the verdict. Nonetheless, we add this additional reasoning on an independent ground. The fact that Dr. Sweet and MGH prevailed on the informed consent claim also is pertinent to the insufficiency of the evidence to show that Dr. Sweet was in

breach of his duty of care to his patients.[12] Under the informed consent doctrine in Massachusetts, "a physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." *Harnish v. Children's Hosp. Med. Ctr., 387 Mass. 152, 439 N.E.2d 240, 243 (1982).* Thus, a doctor who proposes an experimental course of treatment must not only tell the patient about the treatment and its consequences, but must also inform the patient that he is conducting an experimental treatment and that the patient is part of a study. The doctor must not only tell the patient the known risks of the treatment, as he would in a conventional setting, but must also inform the patient that there may be unknown risks.[13] Cf. *Moore v. Regents of Univ. of Cal., 51 Cal. 3d 120, 793 P.2d 479, 483, 271 Cal. Rptr. 146 (Cal. 1990)* (holding that in obtaining a patient's consent to a procedure, "a physician must disclose personal interests unrelated to the patient's health, whether

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[12] The plaintiffs argue that the trial court instructed that the jury could find informed consent even if Dr. Sweet and MGH did not provide them with material information as to risks and possible benefits. The transcript does not support that reading. The transcript shows that the trial judge was dealing with the different problem of proximate causation -- whether the decedents would have withheld consent but for lack of information -- which the jury needed to consider. We reject the rest of the plaintiffs' argument that Dr. Sweet failed to disclose material information.

[13] There are now federal regulations in place which deal specifically with what a doctor must tell a patient to obtain informed consent before that patient can become part of a research study. See 1 M.J. Zaremski & L.S. Goldstein, Medical and Hospital Negligence § 15:10 (1995). In addition, some states also have laws that deal with informed consent in the realm of "therapeutic experimental procedures." See, e.g., *Whitlock v. Duke Univ., 637 F. Supp. 1463, 1467-68 (M.D.N.C. 1986).*

research or economic, that may affect the physician's professional judgment"); 1 S.E. Pegalis & H.F. Wachsman, American Law of Medical Malpractice 2d § 4:1, at 185-86, 189 (1992) ("When human research is being conducted, standards governing disclosure are considerably different from those in the therapeutic setting.").

Defendants argue that if Heinrich and Sienkewicz were adequately informed about the treatment, its experimental nature, and its known risks, and agreed to undergo the treatment nonetheless, then Dr. Sweet and MGH cannot be liable for performing the very treatment to which the patients agreed.[14] On the facts of this case, we agree with the argument.

While there are surely fact patterns where the defendants' argument would be invalid, this case does not fit within them. This is not an instance in which the doctor fully informs the patient about a certain treatment, but then does something at variance with the described treatment; that would be independently negligent and falls below the standard of care. An example would be if a doctor were to fully inform a patient that he will be performing a certain surgery, and then performs the surgery, but leaves the scalpel in the patient's body. Nor is this a situation where the doctor fully informs the patient about an overtly negligent procedure with no possible benefits to the patient, and then performs that procedure. For example, if a doctor were to inform the patient that he would be performing a certain surgery and that he would be leaving the scalpel in the patient's body after the surgery, even if a patient may have

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[14] Plaintiffs argue that because defendants did not bring to the trial court's attention any alleged inconsistency in the verdict, defendants have waived the claim that the verdicts cannot stand because they are inconsistent. *Masure v. Donnelly, 962 F.2d 128, 134 (1st Cir. 1992).* However we do not understand defendants to be making an inconsistency argument, per se, but rather to be using the informed consent verdict in their favor as further evidence that there was no evidentiary support for a finding of negligence.

ignorantly agreed to this procedure, the doctor's actions would still fall below the standard of care, constituting negligence.

The district court, presumably, was alluding to these situations when it said that informed consent does not "operate[] as a defense to a claim of negligence in Massachusetts." Heinrich V, *118 F. Supp. 2d at 91.* These situations do not exist here. There is no evidence to show that the procedure which Dr. Sweet performed was any different from the procedure about which he informed his patients, and there is no evidence to show that what he proposed to his patients was blatantly negligent. The informed consent verdict for the defendants also means that the jury rejected plaintiffs' theory that Dr. Sweet concealed what he knew about the danger of BNCT from the plaintiffs, thus narrowing the plaintiffs' theory to the grounds discussed and rejected earlier.

In summary, the evidence presented at trial to show that Dr. Sweet violated the standard of care had several fatal flaws. The evidence from the plaintiffs' experts that Dr. Sweet did not conform to the applicable standard of care in 1960-61 was wholly inadequate. The evidence was not linked to the state of Dr. Sweet and his team's knowledge at the time the trials took place, and was largely based on articles written by Dr. Sweet and other members of his team about the BNCT trials and their weaknesses after the trials had ended and the authors had compiled and analyzed the data obtained from the trials. In contrast, there was strong evidence from the defendants' experts that Dr. Sweet did act within the standard of care at that time. In addition, the documentary evidence, including the letters, memoranda, and articles from before 1960, does not show that Dr. Sweet and his team knew that BNCT had no therapeutic value. Furthermore, the BNCT treatments were reviewed and approved by three different committees at MGH and one committee at MIT before they were conducted. Lastly, the defendants' argument is buttressed by the fact that the jury ruled in favor of the defendants on the informed consent claim.

V.

This is a difficult case. What is at stake is the medical treatment of two patients and the professional reputations of individuals and institutions based on services performed over four decades ago. The bar to be surmounted in litigation over current charges of malpractice is a demanding one. That bar cannot be lowered to compensate for absence of relevant experience, fading memory, or lack of documentary evidence. Conclusory opinions, unattached to predicate evidence of existing standards, cannot fairly fill the void.

The district court's judgment for the United States is affirmed. The jury verdict for the plaintiffs on the negligence and wrongful death claims is vacated and we direct entry of judgment for the defendants Dr. Sweet and MGH. No costs are awarded.

ENTERED: Circuit Judge Lynch
8/27/02

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 97-12134-WGY

EVELYN HEINRICH on behalf of her husband GEORGE HEINRICH, HENRY M. SIENKEWICZ, JR. on behalf of his mother EILEEN ROSE SIENKEWICZ,[1] Plaintiffs,

v.

WILLIAM H. SWEET, M.D., Trustee of the Lee Edward Farr Trust dated 1/11/71, as amended,[2] THE ESTATE OF LEE EDWARD FARR,[2] M.D., ASSOCIATED UNIVERSITIES, INC.,[2] MASSACHUSETTS GENERAL HOSPITAL, MASSACHUSETTS INSTITUTE OF TECHNOLOGY,[3] and THE UNITED STATES OF

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[1] This case originated as a putative class action, but class action status was denied. See Docket no. 271. The claims of the originally-named plaintiffs Joseph Mayne and Walter Carl Van Dyke were dismissed pre-trial. See Docket no. 217. The claim of the later-added plaintiff, Marc Oddo, has been severed and proceeds as an independent action. See Docket nos. 335, 349.

[2] All claims against each of these defendants were directed out of the case. See Docket no. 246.

[3] The jury found for Massachusetts Institute of Technology upon all claims. See Docket no. 268.

AMERICA,[4] Defendants.

September 29, 2000

MEMORANDUM AND ORDER

JUDGE WILLIAM G. YOUNG

DISPOSITION:

Defendants' Motion for Reduction of Jury Verdict GRANTED [docket no. 315]. Mass General's Motion for Judgment as a Matter of Law on Charitable Immunity DENIED [docket no. 338].

INTRODUCTION

The principal events in this case took place during the 1950s and 1960s. Against all odds, the plaintiffs Evelyn Heinrich ("Heinrich") and Henry M. Sienkewicz ("Sienkewicz") (collectively "the Plaintiffs"), after protracted pre-trial proceedings,[5] eventually brought the defendants William Sweet, M.D. ("Sweet") and Massachusetts General Hospital ("Mass General") (collectively "the Defendants") to

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[4] The Court granted the United States' motion for judgment pursuant to the Federal Tort Claims Act's government contractor exception in an opinion dated February 9, 2000. See Heinrich v. Sweet, 83 F. Supp. 2d 214, 224 (D. Mass. 2000).

[5] This action has already been the subject of four written opinions. A more detailed account of the facts can be found in those opinions. See Heinrich v. Sweet, 44 F. Supp. 2d 408 (D. Mass. 1999) ("Heinrich I"); Heinrich v. Sweet, 49 F. Supp. 2d 27 (D. Mass. 1999) ("Heinrich II"); Heinrich v. Sweet, 62 F. Supp. 2d 282 (D. Mass. 1999) ("Heinrich III"); Heinrich v. Sweet, 83 F. Supp. 2d 214 (D. Mass. 2000) ("Heinrich IV").

bay before a jury of the people. After twenty days of trial, the jury awarded Heinrich $ 250,000 in compensatory damages on her negligence claim and $ 250,000 on her wrongful death claim against both Defendants and awarded punitive damages of $750,000 against Sweet and $1,250,000 against Mass General. The jury awarded Sienkewicz $500,000 in compensatory damages on his negligence claim and $2,000,000 on his wrongful death claim against both Defendants and awarded punitive damages of $1,000,000 against Sweet and $ 2,000,000 against Mass General. Now the question is whether the Plaintiffs can hang onto these verdicts.

This opinion addresses three post-trial issues -- the "Motion for Reduction of Jury Verdict in Accordance with Mass. Gen. Laws c. 229, § 2 (1958 ed.)," Mass General's contention that it is not vicariously liable for the actions of Sweet, and Mass General's "Motion for Judgment as a Matter of Law upon the Issue of Charitable Immunity." Each of these issues is addressed in turn.

ANALYSIS

A. Motion for Reduction of Jury Verdict

Sweet and Mass General make two distinct arguments that are closely intertwined. Both contentions require this Court to determine whether the wrongful death statute applicable to this case is the one that was in existence at the time of the deaths of Heinrich's husband and Sienkewicz' mother (the 1961 statute), or the one that was in place at the time the tortious conduct was discovered (the current statute). First, the Defendants argue that Heinrich's and Sienkewicz' damages should be limited to those contained in the 1961 statute and not the more sweeping damages available in the current statute. Second, they contend that the 1961 statute had a one-year statute of limitations that bars the present action.

1. Previous Rulings

Because all the parties either rely on or take issue with this Court's previous conclusions regarding the applicable statute and statute of limitations issues, a brief review is necessary.

In Heinrich I, the Court addressed the Federal Tort Claims Act claims, specifically the jurisdictional bar contained in 28 U.S.C. § 2401(b). Section 2401(b) provides that a tort action against the United States is forever barred unless "it is presented in writing to the appropriate Federal agency within two years after such claim accrues . . . ." 28 U.S.C. § 2401(b). The issue before the Court was when the claim accrued.

The Court noted that the time of accrual was a question of federal law under the Act. See Heinrich I, 44 F. Supp. 2d at 415 n.8. Although the general rule is that a claim accrues at the time of injury, the Court relied on a Supreme Court decision and applied the discovery rule under federal law. Pursuant to the discovery rule analysis, the claims against the United States were tolled until the plaintiffs discovered or reasonably should have discovered the tortious conduct. See id. at 415. Thus, the procedural bar created by the tort claims act statute of limitations was hurdled.

In the next opinion, the Court addressed the statute of limitations for the other federal claims. Because the other federal causes of action did not have an express statute of limitations period, the Court "borrowed" from state law.

Accordingly, the Court turned to Mass. Gen. Laws ch. 260, § 2A which provides that actions of tort "shall be commenced only within three years next after the cause of action accrues." Mass. Gen. Laws ch. 260, § 2A. Because the claims were under federal law, the Court again relied on federal law to determine when the cause of action accrued and held, as it did

in Heinrich I, that the claims were timely pled. See Heinrich II, 49 F. Supp. 2d at 36-37.

Significant to the discussion here, the Court dismissed Mass General's assertion that the Court ought look to the statute of limitations statute in effect between 1951 and 1961 because that was when the injuries occurred. See id. at 36 n.9. The Court concluded that it would apply the statute of limitations in effect when the cause of action arose. Because "the federal causes of action in these cases did not 'arise' or 'accrue' until 1995, when the Plaintiffs became aware of the alleged true nature of the experiments," the Court relied on the most recent statute. Id. Important to the discussion ahead is that the Court treated the words "arise" and "accrue" as synonymous.

In the third opinion, the Court addressed the statute of limitations defense as it related to the various state law claims. See Heinrich III, 62 F. Supp. 2d at 304-05. Under Massachusetts law, the Court concluded that the statute of limitations had been tolled by both the doctrine of fraudulent concealment contained in Mass. Gen. Laws ch. 260, § 12 and the discovery rule, which was added to the wrongful death statute by amendment in 1989. See Heinrich III, 62 F. Supp. 2d at 305.

As to fraudulent concealment, the Court relied on the fiduciary duty imposed on doctors to disclose known possible causes of actions to patients fully. See id. Because the Massachusetts' plaintiffs alleged that "they did not gain actual knowledge of the 'true nature' of the [boron neutron capture therapy] experiments until 1995, . . . their claims [were] not time-barred under Massachusetts law." Id.

Additionally, the Court addressed the retroactive application of the discovery rule to the claims asserted under the Wrongful Death Statute. See id. at 305. Mass General

pointed out that the statute in effect at the time of the death did not contain a discovery tolling provision. The Court concluded, however, that the 1989 amendment to the Wrongful Death Statute applied retroactively to deaths that occurred prior to the amendment but were discovered after the amendment was in effect. See id. Thus, the Plaintiffs' Massachusetts claims were also saved by the discovery rule.

Equally important, during the conference concerning the preliminary charge to the jury, the Court explicitly stated that the 1995 version of the Massachusetts Wrongful Death Statute applied:

The death statute is procedural. The version of the wrongful death statute that governs is the version at the time the cause of action accrued, not at the time the injections took place. That is, it's the more recent version of the wrongful death statute we're going to use, the one without the limitation and the limitation on punitive damages. Sweet's Mem. in Supp. of Mot. for Reduction of Jury Verdict at 4 (quoting Tr. of Proceedings, Sept. 10, 1999 at 3-4).

In accordance with the construction thus adopted, the factual aspects of the statute of limitations question were presented to the jury. The jury determined that the statute of limitations had been tolled and that the action was timely brought. The Defendants failed to object to the instructions provided to the jury and a review of the jury instructions indicates that they were consistent with Massachusetts law.

2. Applicable Statute

The question remains: did the Court apply the right statute? Answering this question drastically affects the liability of the Defendants. The Court, discussing the federal claims in Heinrich II, stated that it would apply the statute of limitations

in effect when the action "arises" or "accrues." See Heinrich II, 49 F. Supp. 2d at 37 n.9. Relying on the discovery rule and the doctrine of fraudulent concealment, the Court determined that the action accrued in 1995, when the plaintiffs discovered the tortious conduct. Based on this conclusion, the Court later applied the damage provisions available in the current wrongful death statute. In this case, the Court's determination of whether the discovery rule should be retroactively applied has a substantial impact on the extent of the liability of these Defendants. The Court's analysis needs to be revisited in light of the current motion. Cf. Carter v. Supermarkets Gen. Corp., 684 F.2d 187, 191 n.9 (1st Cir. 1982) (when a statute of limitations does not affect defendant's liability, it may be treated retroactively), disagreed with on other grounds by Burnett v. Grattan, 468 U.S. 42, 46 n.9, 82 L. Ed. 2d 36, 104 S. Ct. 2924 (1984).

a. The Wrongful Death Statute

In 1961, the Massachusetts Wrongful Death Statute provided:

A person who (1) by his negligence causes the death of a person in the exercise of due care, or (2) by wilful, wanton or reckless act causes the death of a person . . . shall be liable in damages in the sum of not less than two thousand nor more than twenty thousand dollars, to be assessed with reference to the degree of his culpability . . . . Damages under this section shall be recovered in an action of tort by the executor or administrator of the deceased. No recovery shall be had under this section for a death which does not occur within two years after the injury which caused the death. An action to recover damages under this section shall be commenced within one year from the date of death or within such time thereafter as is provided by sections four, four B, nine or ten of chapter two hundred and sixty.

Mass. Gen. Laws ch. 229, § 2 (1958 ed.). If this is the proper statute, the Court must cap the damages[6] and apply the one-year statute of limitations, which is triggered by the death and tolled only by the provisions of chapter 260, in this case fraudulent concealment.

The wrongful death statute went through a variety of permutations through the years. See, e.g., Gen. Ct. of Mass. ch. 506 (1947); Gen. Ct. of Mass. ch. 427 (1949); Gen. Ct. of Mass. ch. 238 (1958); Gen. Ct. of Mass. ch. 666 (1967). Each change was accompanied by a specific effective date. For example, in 1962 the Massachusetts legislature raised the minimum and maximum amount of damages from $ 2000 and $ 20,000 to $ 3,000 and $ 30,000 respectively, see Gen. Ct. of Mass. ch. 306, § 1 (1962), and interestingly, the legislature was very specific regarding the applicability of the amendment. "This act shall take effect on [Jan. 1, 1963] and shall apply only to actions for death resulting from injuries sustained or accidents occurring on or after said date." Id. § 2. In order to avoid confusion, the legislature also emphasized that "the provisions of law . . . in effect from time to time prior to the effective date of this act, shall continue to be applicable to such actions resulting from injuries which were sustained or accidents which occurred prior to the effective date of this act . . . ." Id. This careful recitation, or some form of it, was present in all the amendments prior to the 1973 amendment.

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[6] Actually, the error goes deeper because the jury was never instructed to assess damages based on culpability. As a practical matter, however, the Defendants, wisely pursuing an intelligent cost-benefit analysis, seek not a new trial but a reduction in the wrongful death damages to the $ 20,000 statutory maximum contained in the 1961 version of the statute.

In 1973, the legislature radically changed the damages allowed under the statute and slightly altered the statute of limitations. See Gen. Ct. of Mass. ch. 957 (1973). One change shifted the damage award from purely punitive damages to both punitive and compensatory damages. See MacCuish v. Volkswagenwerk A.G., 22 Mass. App. Ct. 380, 394 n.19, 494 N.E.2d 390 (1986), aff'd, 400 Mass. 1003, 508 N.E.2d 842 (1987) (noting that, in 1973, "the Governor favored the proposed legislation insofar as it provided that recovery for wrongful death, which up to that time was determined on a punitive basis, would be compensatory").[7] The other, more significant change, removed the cap on punitive damages that had been present since the statute's inception in 1898. See id. at 399 n.27. In addition, the limitations period was extended from two years to three years. See Gen. Ct. of Mass. ch. 957, § 1 (1973). The 1995 version applied by the Court in this case reflects these changes:

A person who . . . causes the death of a person, . . . shall be liable in damages in the amount of: (1) the fair monetary value of the decedent to the persons entitled to receive the damages . . . including but not limited to compensation for the loss of the reasonably expected net income, services, protection, care, assistance, society, companionship, comfort, guidance, counsel, and advice of the decedent . . .; (2) the reasonable funeral and burial expenses of the decedent; (3) punitive damages in an amount of not less than five thousand dollars in such case as the decedent's death was caused by the malicious, willful, wanton or reckless conduct of the defendant . . . . An action to recover damages under this section shall be commenced within three years from the date of death . . . .

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[7] Contrary to the Defendants' position that there were no punitive damages allowed under the wrongful death statute, the damages were viewed as entirely punitive. The statutory cap, however, limited liability.

Mass. Gen. Laws ch. 229, § 2 (1995).

Unlike the earlier amendments, it was determined in the 1973 amendment that "this act shall take effect on [Jan. 1, 1974], and shall apply to causes of action arising on or after said date." Gen. Ct. of Mass. ch. 957, § 2 (1973). Thus, whether the 1973 damage provisions apply to the Plaintiffs depends on whether their cause of action for wrongful death "arose" in 1961, at the time of their deaths, or after January 1, 1974, when the tortious conduct was discovered.

As already discussed, this Court determined that the "causes of action in these cases did not 'arise' or 'accrue' until 1995, when the Plaintiffs became aware of the alleged true nature of the experiments." Heinrich II, 49 F. Supp. 2d at 37 n.9; see Heinrich III, 62 F. Supp. 2d at 305 (stating that discovery rule analysis under federal law "applies with equal force under Massachusetts discovery rule principles"). This conclusion came, in part, from the retroactive application of the discovery rule that was added to the wrongful death statute by a 1989 amendment. The amended statute has since provided:

An action to recover damages under this section shall be commenced within three years from the date of death, or within three years from the date when the deceased's executor or administrator knew, or in the exercise of reasonable diligence, should have known of the factual basis for a cause of action . . . .

Mass. Gen. Laws ch. 229, § 1 (2000); see Gen. Ct. of Mass. ch. 215 (1989). It is recognized that the discovery rule delays accrual until discovery. See Pobieglo v. Monsanto Co., 402 Mass. 112, 116, 521 N.E.2d 728 (1988). While this Court used the word "accrue" and "arise" synonymously, see Heinrich II, 49 F. Supp. 2d at 37 n.9, it is not clear that this was precise. If it is, the retroactive application of the discovery rule has a

significant impact on the substantive rights of the defendant. See Fontaine v. Ebtec Corp., 415 Mass. 309, 319-20, 613 N.E.2d 881 (1993). In Fontaine, the Supreme Judicial Court stated:

> We have recognized that legislation limiting or increasing the measure of liability, while arguably remedial in the broad sense of that word, generally is considered to impair the substantive rights of a party who will be adversely affected by the legislation. In the absence of a provision mandating retrospective application, we have not assumed that such legislation applies to claims arising prior to enactment.

Id. at 319. Thus, a discussion of the power of word choice is in order.

b. Arise, Accrue -- What's the Difference?

It is true that, at times, Massachusetts courts have used the terms arise and accrue interchangeably, as this Court did in Heinrich II. According to Black's Law Dictionary, however, there is a subtle, yet important, difference between the two words. "Accrue" means "to come into existence as an enforceable claim or right." Black's Law Dictionary 21 (7th ed. 1999). In contrast, "arise" means "to originate" as in "a federal claim arising under the U.S. Constitution." Id. at 102. Thus, based solely on the legal definitions, it appears that the Plaintiffs' claims originated or arose under the 1961 statute but did not accrue or come into existence until discovery in 1995. In any event, while Black's is a starting point, this Court ultimately must rely on Massachusetts law.

Massachusetts courts consistently apply the statute in effect at the time of death, even if the statute of limitations was tolled. See Gaudette v. Webb, 362 Mass. 60, 63, 284 N.E.2d 222 (1972); Bickford v. Furber, 271 Mass. 94, 97, 170 N.E. 796

(1930), overruled in part on other grounds by Gaudette, 362 Mass. at 63; Jenkins v. Jenkins, 15 Mass. App. Ct. 934, 935, 444 N.E.2d 1301 (1983) (rescript opinion); Gouras v. Barchi, 5 Mass. App. Ct. 845, 846, 364 N.E.2d 213 (1977) (rescript opinion); see also Anderson v. W.R. Grace & Co., 628 F. Supp. 1219, 1225 n.2 (D. Mass. 1986) (Skinner, J.); Ellis v. Ford Motor Co., 628 F. Supp. 849, 852 (D. Mass. 1986) (Freedman, J.).

Further, a tolling provision, whether it be fraudulent concealment or the discovery rule, does not alter the date on which the action arose. The court's analysis in Ellis is instructive on this point. In Ellis, the court was faced with two plaintiffs that died as a result of a car accident that occurred in 1973. See Ellis, 628 F. Supp. at 851. Janet Parker died instantaneously; however, Robert Parker did not die of the injuries sustained in the accident until 1983. See id. A cause of action to recover for both deaths was brought in 1983. The court engaged in two distinct analyses based on the differing dates of death. See id. at 852, 859. As to Janet Parker, the court applied the 1973 statute to the claims brought on behalf of her children. In 1973, the wrongful death statute provided that an action must be commenced within one year of the date of death. See id. at 859. While the eleven-year delay obviously exceeded the one-year statute of limitations, the court held that it had been tolled by the minority of the children. See id. at 860. Significantly, the tolling provision relied on by the court did not change the time in which the action "arose." The tolling provision simply stopped the running of the statute of limitations contained in the 1973 statute.

Moreover, the Massachusetts courts have declined to apply the 1973 amendment retroactively to deaths occurring prior to its effective date. See Owen v. Meserve, 381 Mass. 273, 276, 408 N.E.2d 867 (1980); Minkley v. MacFarland, 371 Mass. 891, 891, 356 N.E.2d 1391 (1976) (rescript opinion); Gouras,

5 Mass. App. Ct. at 846. In Minkley, an action was brought by the decedent's wife following his death on August 16, 1973 -- four months prior to the effective date of the amendment. The family sought compensatory and punitive damages. The Supreme Judicial Court declined to recognize the compensatory damages as part of the statutory claim. In rejecting the claim, it limited its holding, stating "nothing we say here as to actions for wrongful death is applicable to claims arising on or after January 1, 1974." Minkley, 371 Mass. at 891; see also Owen, 381 Mass. at 276 ("The governing statute in Massachusetts in 1971 defined the beneficiaries of such recovery, fixed maximum and minimum dollar amounts, and provided for assessment of damages with reference to the degree of the defendant's culpability."); Gouras, 5 Mass. App. Ct. 845 at 846, 364 N.E.2d 213 ("Inasmuch as the cause of action here arose prior to the effective date of the amendment of G.L. c. 229, s. 2, by St. 1973, c. 699, that statute has no application in this case.").

In addition, outside the context of the wrongful death statute, it is evident that both the courts and the legislature recognize the difference between "accrue" and "arise." See Mass. Gen. Laws ch. 258, § 4; George v. Town of Saugus, 394 Mass. 40, 41, 474 N.E.2d 169 (1985). In George, the Supreme Judicial Court was faced with distinguishing "accrue" from "arise" in the context of the Massachusetts Tort Claims Act. The Act provided that an action against a public employee was barred unless "the claimant shall have first presented his claim . . . within two years after the date upon which the cause of action arose . . . ." Mass. Gen. Laws ch. 258, § 4. Additionally, a civil action was barred if it was "brought more than three years after the date upon which such cause of action accrued." George, 394 Mass. at 41 n.1. The plaintiff, a minor at the time of the injury, failed to present her claim until she reached the age of majority, nearly three years later. She sought to apply the tolling provisions for minors to the presentment

requirement. The Supreme Judicial Court refused, instead holding that the statute required presentment to be made within two years of the injury -- the date on which the action arose. In contrast, the date of accrual, triggering the three-year statute of limitations, was delayed until majority. See id. at 42 n.3.

Thus, there is ample evidence within Massachusetts statutes and case law to support a conclusion that "arise" and "accrue" are distinct concepts that bring different meaning to a statute. A review of the law reveals that the Court erred in its previous analysis. Based on the foregoing, this Court rules that the Plaintiffs' claims for wrongful death arose in 1961, even if they accrued at a later date. Accordingly, the damage provisions in the 1961 statute are applicable.

Damages under the wrongful death statute are limited to twenty thousand dollars.

3. Tolling

Not content, Sweet and Mass General contend that the one-year statute of limitations contained in the earlier wrongful death statute bars all recovery.

The next step in the analysis is thus to determine whether the one-year statute of limitations was tolled by an applicable tolling provision. In Heinrich III, the Court ruled that the statute of limitations was tolled by fraudulent concealment. See Heinrich III, 62 F. Supp. 2d at 304. In addition, the Court applied the discovery rule, added to the Wrongful Death Statute in 1989, retroactively. See id. at 305. As a result, the statute was tolled until, at the earliest, 1995. Sweet and Mass General challenge both grounds. See Defs.' Mem. in Supp. of Mot. for a New Trial at 14; Defs.' Mem. in Supp. of Renewed Mot. for J.N.O.V. at 18. Chapter 260, section 12 provides:

If a person liable to a personal action fraudulently conceals the cause of such action from the knowledge of the person entitled to bring it, the period prior to the discovery of his cause of action by the person so entitled shall be excluded in determining the time limited for the commencement of the action.

Mass. Gen. Laws ch. 260, § 12. In general, this statute requires a plaintiff to show an affirmative act of fraudulent concealment on the part of the defendant. See Maggio v. Gerard Freezer & Ice Co., 824 F.2d 123, 130 (1st Cir. 1987). But in cases in which "a fiduciary relationship exists between plaintiff and defendant [the] mere failure to reveal information may be sufficient to constitute fraudulent conduct for the purposes of section 12." Id.; see also Puritan Med. Ctr., Inc. v. Cashman, 413 Mass. 167, 176, 596 N.E.2d 1004 (1992). The Massachusetts courts have held that "for some purposes (e.g., treatment) the doctor-patient relationship is a fiduciary one, . . . and there may be some circumstances where there is a duty to disclose a cause of action." Fowles v. Lingos, 30 Mass. App. Ct. 435, 441, 569 N.E.2d 416 (1991) (citations omitted). In addition, a physician has a duty of full disclosure under the doctrine of informed consent to alert a patient of the material risks and alternatives to a chosen course of action. See Bourassa v. LaFortune, 711 F. Supp. 43, 47 (D. Mass. 1989) (Harrington, J.); Harnish v. Children's Hosp. Med. Ctr., 387 Mass. 152, 155-56, 439 N.E.2d 240 (1982). Thus, under Massachusetts law, silence can be the equivalent of fraudulent concealment.

Moreover, the Supreme Judicial Court has held that:

An actual knowledge standard applies to a plaintiff who argues that a breach of fiduciary duty of disclosure constitutes fraudulent concealment under G.L. c. 260, § 12. Such a plaintiff need only show that the facts on which the cause of

action is based were not disclosed to him by the fiduciary. The plaintiff is not required to have made an independent investigation.

DeMoulas v. DeMoulas Super Mkts., Inc., 424 Mass. 501, 519-20, 677 N.E.2d 159 (1997) (citation omitted). The law, therefore, places the burden on the fiduciary to disclose the referent facts.

In Heinrich III, the Court ruled that "the Massachusetts Plaintiffs need only show that the private defendants failed to disclose the facts which give rise to a possible cause of action, and that the Massachusetts Plaintiffs did not otherwise gain knowledge of those facts at an earlier time . . . ." Heinrich III, 62 F. Supp. 2d at 304. In general, this statement is true in fiduciary relationships. In the context of the doctor-patient relationship, however, the Massachusetts courts have developed a slightly different standard. The Supreme Judicial Court, in Maloney v. Brackett, 275 Mass. 479, 176 N.E. 604 (1931), ruled that there must be some evidence that "the defendant knew or believed" that she had breached her professional duty. Id. at 484. This Court acknowledged this when it stated "Massachusetts imposes a fiduciary duty on doctors to disclose known possible causes of action to patients." Heinrich III, 62 F. Supp. 2d at 304 (emphasis added). In support of its analysis, this Court cited Bourassa v. LaFortune, 711 F. Supp. 43 (D. Mass. 1989). See id.

Sweet and Mass General claim that this Court's reliance on Bourassa is misplaced because the Massachusetts Appeals Court declined to adopt its holding in Fowles v. Lingos, 30 Mass. App. Ct. 435, 437, 569 N.E.2d 416 (1991). According to the defendants, "to date, no Massachusetts Court has found sufficient facts to impose an affirmative duty of disclosure for purposes of fraudulent concealment in the context of a doctor-patient relationship." Defs.' Mem. in Supp. of Renewed Mot. for J.N.O.V. at 18. The preceding statement is accurate,

but the Court disagrees with the defendants' assessment of the dissonance between Fowles and Bourassa.

Both Fowles and Bourassa relied on the Supreme Judicial Court's decision in Maloney to establish the standard of disclosure in a doctor-patient relationship. See Fowles, 30 Mass. App. Ct. at 440-41; Bourassa, 711 F. Supp. at 47. In the context of fraudulent concealment, the Supreme Judicial Court stated that "the failure of a doctor to disclose a cause of action to a patient could not be found to be a breach of his professional duty without evidence that he knew or believed . . . he had performed or assisted in the performance of an unnecessary operation . . . ." Maloney, 275 Mass. at 484. Thus, the Supreme Judicial Court required that there be evidence that the doctor knew or believed that she had erred.

The Fowles court had no evidence before it that a cause of action had been known. Indeed, there was a strong difference of opinion regarding whether the doctor had even acted negligently. According to the court in Fowles, "[a] plaintiff does not establish fraudulent concealment . . . 'by showing only that there is a difference of opinion concerning the applicable standard of care.'" Fowles, 30 Mass. App. Ct. at 441 (quoting Geisz v. Greater Baltimore Med. Ctr., 313 Md. 301, 330, 545 A.2d 658 [1988]).

In Bourassa, the court concluded that, based on the language of Maloney, "if a doctor knows or believes that a cause of action exists and fails to disclose it to the plaintiff, he will have breached his fiduciary relationship . . . thus tolling the statute of limitations." Bourassa, 711 F. Supp. at 47. Given the facts before it, the court ruled that there was sufficient evidence to overcome summary judgment on a statute of limitations defense. See id. at 48.

The Massachusetts Court of Appeals, in Fowles,

distinguished the facts in Bourassa from those before it: "We do not know what material concerning that issue was before the judge in Bourassa. What was here presented to show fraudulent concealment was insufficient . . . ." Fowles, 30 Mass. App. Ct. at 441. The court went on to note that "the facts in this case are distinguishable from those in Bourassa." Id. at 442 n.9. Implicit in the court's language in Maloney and consistent with Fowles is that "if evidence had been presented tending to prove that the defendants did not believe in good faith that the plaintiff's operation was advisable, the court would have ruled differently." Bourassa, 711 F. Supp. at 47.

In addition, because the retroactive application of the discovery rule does not affect the substantive rights of the defendants, the statute of limitations was tolled by the discovery rule as well. See Carter, 684 F.2d at 191 n.9 ("Massachusetts follows the general rule that, absent clear legislative intent, statutes affecting substantive rights are prospective, whereas statutes affecting procedure or remedies may be retroactive."). It has been held that the discovery rule establishes the date of accrual. See Pobieglo v. Monsanto Co., 402 Mass. at 117. Because the date of accrual and the date the action arose can be different dates, the retroactive application of the discovery rule amendment does not influence the Court's conclusion regarding the applicable statute for damages. As a result, the Court's reasoning in Heinrich III, retroactively applying the discovery rule, 62 F. Supp. 2d at 305, remains intact.

More important at this juncture of the proceedings is the jury's findings. The statute of limitations question was ultimately presented to the jury. The Defendants did not object to the Court's jury instructions at the time of the charge, nor do they quarrel with them in their current papers. The jury found that the statute of limitations had been tolled. The jury charge accurately reflects the law as interpreted by this Court.

Mass General suggests that because the jury found for the Defendants as to informed consent, it was inconsistent to find that the statute of limitations was tolled by fraudulent concealment. Its analysis, however, confuses two distinct concepts. A doctor could inform a patient of all the risks of a procedure as well as the uncertainty of the outcome but nonetheless fail to disclose that the procedure itself was negligent or the manner in which it was performed was negligent. Implicit in the doctor-patient relationship is an understanding that the doctor is acting in the best interest of the patient and within the bounds of medical ethics. While Dr. Sweet may have informed the Plaintiffs that the treatment was risky and uncertain, he failed to disclose that performing the experiments on human beings was negligent. This is what the jury found, and it is consistent.

Accordingly, the motion of Sweet and Mass General to reduce the jury verdict is ALLOWED and, upon this cause of action, Sweet is adjudged liable for punitive damages alone in the amount of $ 20,000 -- the maximum the Massachusetts Wrongful Death Statute would allow at the time the Plaintiffs' wrongful death cause of action arose. Mass General would stand in the same position save that it now trims its sails in an attempt to claw its way free altogether.

B. Vicarious Liability

In an attempt to divorce itself completely from any responsibility, Mass General argues that the evidence was insufficient for it to be held liable for the conduct of Sweet. See Mass General's Mem. in Supp. of Mot. for J. on Charitable Immunity at 17. In a conclusory two-paragraph argument, Mass General "submits that the evidence presented at trial did not satisfy the plaintiff's burden of proving an agency relationship between Dr. Sweet and [Mass General]." Id. at 18.

The vicarious liability of hospitals for the negligent act of a physician is slightly different than that applied to standard employer-employee relationships under Massachusetts law. See Miller v. Kurkjian, 1999 Mass. Super. LEXIS 47, No. CIV.A. 95-1723 B, 1999 WL 176911, at *2-*5 (Mass. Super. Feb. 23, 1999) (Gants, J.) (describing the evolution of vicarious liability in Massachusetts). In general, control of an agent's activities has been the guiding principle in deciding cases that involve an assertion of vicarious liability. See Kelley v. Rossi, 395 Mass. 659, 662- 63, 481 N.E.2d 1340 (1985) called into doubt on other grounds by Miller, 1999 WL 176911, at *6-*7. Initially, the Supreme Judicial Court construed the term "control" narrowly, limiting it to instances in which the employer had the "right of control" over the specific conduct in question. See Khoury v. Edison Elec. Illuminating Co., 265 Mass. 236, 238-39, 164 N.E. 77 (1928), overruled in part by Konick v. Berke, Moore Co., Inc., 355 Mass. 463, 468, 245 N.E.2d 750 (1969). According to the court, "the employee must be subject to control by the employer, not only as to the result to be accomplished but also as to the means to be used." Khoury, 265 Mass. at 238. Thus, it was possible "for a person [to] be an agent or a servant as to one part of an undertaking, and an independent contractor as to other parts." Id. at 239.

Later, the Supreme Judicial Court broadened the scope of acts included within vicarious liability. See Konick, 355 Mass. at 468. Instead of requiring the employer to have control over the precise conduct, liability was found whenever there was an employer-employee relationship and the negligent act was within the scope of the employment. See id. at 467-68. In essence, the "right of control" over the conduct was inferred if the employee was acting "in furtherance of the master's business." Id.

Although the change in Konick appears semantic, the effect is dramatic when the opposing outcomes in the almost identical

fact scenarios of Khoury and Konick are compared. In both instances, an employee was using a personal vehicle to perform company business with the permission of the employer. In Khoury the court concluded that there was no vicarious liability because the employer did not have any control over the employee in the operation of the car or in the car's condition. See Khoury, 265 Mass. at 239-40. In contrast, in Konick, the court applied the broader definition of "control" and concluded that even though the employer did not have control over the employee's operation of the car, liability existed because he was acting "in relation to his duties" to the employer. Konick, 355 Mass. at 468.

It does not appear, however, that the Konick definition extended to physicians. "Because of the high level of skill involved in the practice of medicine, physicians have traditionally been viewed as independent contractors, allowing hospitals and other medical centers to remain exempt from liability for negligent acts of a physician." Chase v. Independent Practice Ass'n, Inc., 31 Mass. App. Ct. 661, 665, 583 N.E.2d 251 (1991) (citing Kelley, 395 Mass. at 662); but see Miller, 1999 WL 176911, at *7 (suggesting it is unclear what formulation of vicarious liability applies to physicians). Despite this broad statement, Massachusetts courts have been willing to hold hospitals or other health care facilities liable in some instances for the negligent conduct of a physician. See Smith v. Steinberg, 395 Mass. 666, 669, 481 N.E.2d 1344 (1985); Kelley, 395 Mass. at 664; McMurdo v. Getter, 298 Mass. 363, 368, 10 N.E.2d 139 (1937). Even so, the test for vicarious liability in this context parallels the one first expressed in Khoury rather than Konick. In short, there has to be evidence that Mass General had control or the right of control over Sweet's actual conduct which is alleged to be negligent, namely the radiation experiments. See Kelly, 395 Mass. at 664; Harnish, 387 Mass. at 159; Chase, 31 Mass. App. Ct. at 665. But see Miller, 1999 WL 176911, at *1-*7

(suggesting that broader formulation of vicarious liability will likely emerge).

There is ample evidence in the record that Mass General exercised or had the right to exercise control and direction over the radiation experiments. Mass General's approval was critical to the ability of Sweet to conduct the experiments. Dr. Sweet made a formal request to use the facilities and reactor at M.I.T only "after extensive discussions with the appropriate authorities at the Massachusetts General Hospital . . . ." Trial Ex. 10 at 1. The request also stated that the experiments had been "approved at [Mass General] by the Surgical Executive Committee, the General Executive Committee of the Staff, and the Board of Trustees." Id. at 2 (internal citations omitted). These same committees also had assessed the "general problem of the responsibility of [Mass General] for its patients during the period they are at as well as travelling [sic] to and from the M.I.T. reactor . . . ." Id. Moreover, the General Director of Mass General, Dr. Clark, appointed a single individual, not Sweet, "with whom M.I.T. authorities may deal on administrative problems and in medico-legal implications of this work." Id. Implicit in the request is that access to the reactor would have been denied without the involvement and approval of Mass General.

The evidence described above is more than adequate to support the conclusion that Mass General exercised or had the right to exercise control and direction over the radiation experiments conducted by Sweet and other physicians at Mass General.[8] Mass General makes no attempt to rebut this evidence, nor does it present any case law that would require

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[8] The Plaintiffs also point to other evidence presented at trial that indicates an agency relationship between Sweet and Mass General. See Pls.' Opp'n to Mot. for J. on Charitable Immunity at 14-16 (citing Trial Exs. 58, 61-64, 67, 71).

this Court to find this quantum of evidence lacking.

Thus, this Court rules that the evidence presented was more than sufficient for Mass General to be held liable for the negligent actions of Sweet.

C. Charitable Immunity

Mass General maintains that complete charitable immunity under Massachusetts common law, as it existed at the time of the treatment, extinguishes its liability. See Mass General's Mem. in Supp. of Mot. for J. on Charitable Immunity at 6. The Plaintiffs agree that the common law and not the statutory law is applicable and further contend that the Court must look to the charitable status of Mass General in 1960 and not its current charter to determine if immunity exists. See Pl.'s Opp'n to Mot. for J. Charitable Immunity at 1-2 n.1. The parties' positions accord with Massachusetts case law.

Shortly after the 1971 enactment of the statute providing for limited charitable liability, Mass. Gen. Laws ch. 231, § 85K, the Supreme Judicial Court determined that this statute did not apply retroactively. See Ricker v. Northeastern Univ., 361 Mass. 169, 172, 279 N.E.2d 671 (1972) ("We perceive no indication that [Mass. Gen. Laws ch. 231, § 85K] has, or was intended to have, any retrospective effect."); see also Perloff v. Symmes Hosp., 487 F. Supp. 426, 429 (D. Mass. 1980) (Zobel, J.) (statute had the effect of barring charitable immunity prospectively only); Johnson v. Wesson Women's Hosp., 367 Mass. 717, 718, 328 N.E.2d 490 (1975) (statute abolishing charitable immunity is not retrospective in effect); Higgins v. Emerson Hosp., 367 Mass. 714, 715, 328 N.E.2d 488 (1975) (same). Consequently, the statute does not apply to injuries that occurred prior to its effective date. See Johnson, 367 Mass. at 718; Higgins, 367 Mass. at 715. Because Heinrich and Sienkewicz both died prior to the statute's enactment, their

claims are governed by the law as it existed at the time of their deaths. It follows logically that the Court would look to the charitable status of Mass General in 1960 to determine the applicability of charitable immunity. If Mass General has the benefit of the defense, it has complete immunity from liability.

1. The Analysis

A review of the early case law explicating charitable immunity reveals that the courts have struggled to define the exact parameters of the doctrine. After reviewing Massachusetts charitable immunity decisions, the First Circuit illustrated the doctrine of charitable immunity in the following manner:

[SEE charitable immunity IN ORIGINAL]

Mason v. Southern New England Conference Ass'n of Seventh-Day Adventists, 696 F.2d 135, 140 n.8 (1st Cir. 1982). According to the First Circuit, the charitable exemption applies only when the activity in question is both charitable and not primarily commercial. See id.

This Court's review of the early Massachusetts case law accords, in most respects, with the First Circuit's analysis. What emerges, although not always clearly elucidated by the courts, is a burden-shifting paradigm. As charitable immunity is an affirmative defense, the defendant bears the burden of going forward with evidence sufficient to warrant the conclusion that it is a public charity. See McDonald v. Massachusetts Gen. Hosp., 120 Mass. 432 (1876) ("The defendant was a public charitable institution under the laws of the Commonwealth."), overruled in part on other grounds by Colby v. Carney Hosp., 356 Mass. 527, 528, 254 N.E.2d 407 (1969). The plaintiff, of course, can rebut this evidence or, alternatively, seek to shoulder the burden of going forward with either evidence that

the defendant was acting outside its charitable corporate powers when the tort occurred, see McKay v. Morgan Mem'l Co-op Indus. and Stores, Inc., 272 Mass. 121, 123, 172 N.E. 68 (1930) (determining whether business conducted was to carry out charitable purpose as described in charter); Holder v. Massachusetts Horticultural Soc'y, 211 Mass. 370, 97 N.E. 630 (1912) (defendant used part of building where accident occurred "for purposes entirely disconnected with those for which the defendant was chartered"); Mason, 696 F.2d at 140 ("We must therefore determine whether the Association's activity was within its corporate powers . . . ."), or evidence that the activity was primarily commercial. See McKay, 272 Mass. at 125. The ultimate burden of persuasion rests on the defendant to establish the affirmative defense.

Describing the analysis is simpler than its actual application, however. Real life activities are not as easily categorized as either the First Circuit's table or this Court's burden-shifting paradigm suggest. Often, the factual predicate of a case crosses boundaries. It has been the unenviable task of the courts to establish either liability or immunity based on the unique facts and circumstances of a particular case.

A second, complicating factor is that even if the Plaintiffs present credible evidence that Mass General was acting outside its charitable corporate powers or that the activity was primarily commercial, the charitable immunity defense is not eliminated. Mass General is correct in contending that its Charter "is prima facie evidence of charitable purpose and operation . . . ." Barrett v. Brooks Hosp., Inc., 338 Mass. 754, 758, 157 N.E.2d 638 (1959), overruled in part on other grounds by Colby, 356 Mass. at 528; see also Boxer v. Boston Symphony Orchestra, Inc., 339 Mass. 369, 372, 159 N.E.2d 336 (1959). Under Massachusetts law, it is well established that there is a difference between a presumption and prima facie evidence. See Commonwealth v. Pauley, 368 Mass. 286,

290-91, 331 N.E.2d 901 (1975); Boxer v. Boston Symphony Orchestra, Inc., 342 Mass. 537, 538, 174 N.E.2d 363 (1961), overruled in part on other grounds by Colby, 356 Mass. at 528; Salter v. Leventhal, 337 Mass. 679, 696-97, 151 N.E.2d 275 (1958); Cook v. Farm Serv. Stores, Inc., 301 Mass. 564, 566-67, 17 N.E.2d 890 (1938). According to the Massachusetts view, a presumption is rebuttable and may be rebutted by evidence warranting a finding contrary to the presumed fact. Once rebutted, the presumption disappears and the party that was aided by the presumption is left with nothing more, perhaps, than an inference of a once presumed fact.

In contrast, prima facie evidence does not disappear, even in the face of evidence warranting a finding to the contrary. Prima facie evidence maintains its evidentiary force, remains in the case, and is accorded "such weight as the jury sees fit to give it." William G. Young et al., Massachusetts Evidentiary Standards 44 (2000); see also Paul J. Liacos et al., Handbook of Massachusetts Evidence § 5.5.3, at 230 (7th ed. 1999). In other words, rebuttal evidence simply avoids a mandatory finding of charitable immunity, but it does not result in a mandatory finding that the defense is inapplicable. The applicability or inapplicability of the defense is a decision for the fact finder.

2. The Case Law and Its Application

Charitable immunity was based on the reasoning that it is improper to divert funds for tort judgments that were donated for charitable purposes. See, e.g., Roosen v. Peter Bent Brigham Hosp., 235 Mass. 66, 68, 126 N.E. 392 (1920), overruled in part on other grounds by Colby, 356 Mass. at 528; McDonald, 120 Mass. at 432. This "trust fund" rationale did not extend, however, to liability for torts committed in the course of revenue-generating activities even if the money was to be applied to the charitable purpose. See McKay, 272 Mass.

at 124; Mason, 696 F.2d at 139. When actually faced with factual situations that involved revenue production, the courts further refined the analysis to allow immunity if the revenue was produced only incidentally to some charitable activity. See Boxer, 342 Mass. at 539. In addition, immunity was allowed for conduct that was only indirectly linked to an institution's charitable purpose but that was not for revenue production. See Ricker, 361 Mass. at 172.

The case law indicates that the protection afforded by charitable immunity is most often lost due to the commercial nature of an activity. Thus, courts have emphasized the First Circuit's "primarily commercial" box. According to the First Circuit, "'directly' charitable activities are meant to be contrasted with those activities whose thrust is commercial, rather than with all the other forms of activities that may in some sense be only indirectly charitable." Mason, 696 F.2d at 139. What is obscured by this statement, and undeveloped by the case law, is the box labeled "non-charitable" by the First Circuit or, in this case, the availability of evidence that the institution acted ultra vires.

This undeveloped area of the law is exactly what is at issue here. The Plaintiffs do not attack Mass General's status as a charitable institution, nor do they argue that Sweet's research was primarily commercial. Instead, the Plaintiffs argue that Mass General was acting outside of its charitable purposes when it conducted the boron neutron experiments on human beings.

In response, Mass General properly argues that it has met its initial burden of production under the affirmative defense of charitable immunity. The burden of going forward is now on the Plaintiffs to present evidence that warrants a finding to the contrary. As already noted, however, evidence rebutting the prima facie case only avoids a mandatory finding that Mass

General is protected by the charitable immunity doctrine, it does not automatically result in a finding for the Plaintiffs.

The parties dispute what rebuttal evidence is necessary. Mass General claims that the Plaintiffs must establish that the research was primarily commercial while the Plaintiffs contend that evidence that Mass General acted ultra vires will suffice. The language of the cases supports the Plaintiffs' averments that the charitable immunity defense can be rebutted by evidence that the charitable institution was acting ultra vires.

In Reavey v. Guild of St. Agnes, 284 Mass. 300, 187 N.E. 557 (1933), the Supreme Judicial Court declared that "[a] charitable corporation is not liable for negligence in the course of activities within its corporate powers carried on to accomplish directly its charitable purpose." Id. at 301 (1933). The court went on to find "nothing in the allegations shows that painting the defendant's building was not within its corporate powers." Id. at 303. The court separately addressed the issue of whether the painting was "primarily commercial." Id.

More than a decade later, the court again approached charitable immunity with a similar analysis. See Carpenter v. Young Men's Christian Ass'n, 324 Mass. 365, 370-71, 86 N.E.2d 634 (1949). In Carpenter, a young boy was injured at a playground owned and operated by the YMCA, an acknowledged charitable organization. It was undisputed that the playground was not a business enterprise for profit. See id. at 370. Even though the court determined that the YMCA was a charity and the activity was not primarily commercial, its analysis was not complete. The plaintiff contended that operation of the playground was outside the corporation's charitable purpose. The court concluded otherwise:

Nor did the defendant lose its charitable character because of operating a playground for young children of both sexes, the

while its statutory purposes were for the "purpose of improving the spiritual and mental condition of young men." Provided there is adherence in the main to the declared purpose of the charity, incidental variations do not destroy the right to exemption.

Id. at 371.

In Barrett, the court addressed which party had the ultimate burden of persuasion regarding whether the charitable organization was acting ultra vires. See Barrett, 338 Mass. at 757. The court concluded that once an organization established its charitable purpose through public documents it was not "incumbent upon that corporation [to shoulder] the further obligation to go on and prove . . . it has not been operating ultra vires . . . ." Id. Thus, the burden shifts to the plaintiff to introduce evidence of ultra vires activity. Again, as part of the analysis in Boxer, the court ruled "there was no evidence to show that in any aspect the defendant in 1955 was acting beyond the scope of its charter. . . ." Boxer, 342 Mass. at 538.

As the case law indicates, the Plaintiffs are not limited to presenting evidence that Mass General's activity was primarily commercial. Mass General may also lose its charitable immunity by acting beyond its corporate purpose. The question now becomes whether the Plaintiffs were injured during an activity which was within the scope of Mass General's charitable purpose. If the activity was beyond Mass General's corporate powers, then it may be subject to the ordinary rules of liability.

With the issue defined and the evidentiary framework established, the parties circle, looking for a knock-out punch as matter of law. The Plaintiffs contend that medical research was not included in Mass General's Charter as it existed in 1960. The charitable purpose of the hospital was stated as "the

maintenance of sick[,] poor and lunatic persons, who would otherwise be chargeable to the Commonwealth . . . " Pl.'s Mem. in Opp'n to Mot. for J. on Charitable Immunity App. I at 5. Mass General concedes that the "general charitable purpose of [Mass General] has always been to provide care to the sick" but argues that the "development of new potential treatment modalities . . . is certainly in accordance with that purpose." Def.'s Mem. in Supp. of Mot. for J. on Charitable Immunity at 16.

The Plaintiffs counter that medical research is not an inherent part of the charitable activity of providing care to the sick and indigent. In order to support this assertion, they point to the 1977 Articles of Amendment which expanded Mass General's corporate purpose to include "educational activities and scientific research related to the care of such persons or to the promotion of health and the prevention of disease." Pl.'s Mem. in Opp'n to Mot. for J. on Charitable Immunity App. I at 17. According to the Plaintiffs, the amendment "would be surplusage and the words would have no force and effect" if Mass General's earlier Charter had already provided for such conduct. Id. at 6.[9]

Neither argument is without merit. Moreover, the indefinite posture of the law in this area makes analysis all the more difficult. How activity is characterized impacts the evaluation. Were the experiments, as Mass General asserts, a natural

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[9] The charitable purposes of Brooks Hospital, as stated in Barrett, separately listed the provision of medical services for the sick and the promotion of treatment through "original research and laboratory investigations." Barrett, 338 Mass. at 757. While the court determined that research and laboratory investigations were of "charitable use," it is noteworthy, although not conclusive, that this purpose was separately set forth in the charter rather than assumed within the scope of medical treatment.

extension of the expressed charitable purpose of caring for the sick and insane? Or was the research, as Plaintiffs contend, outside the scope of the charitable purpose because the Plaintiffs were used "in human experiments where there was no reasonable possibility of therapeutic benefit?" Id. at 5.

In general, Massachusetts courts have broadly construed stated charitable purpose. As the Supreme Judicial Court observed in Carpenter, as long as there is "adherence in the main to the declared purpose of the charity, incidental variations do not destroy the right to exemption." Carpenter, 324 Mass. at 371. It is not necessary for the activity explicitly to be expressed in the corporate charter to establish immunity if the activity fits within the "broad general purposes of the charter." Boxer, 342 Mass. at 539. For example, in Enman v. Trustees of Boston University, 270 Mass. 299, 170 N.E. 43 (1930), the court ruled that the maintenance of a dormitory fit within Boston University's educational purpose, see id. at 300. See also Ricker, 361 Mass. at 172. Thus, the Plaintiffs' reliance on the four corners of the charter is misplaced. The fact that research was explicitly added later does not exclude it from the original charitable purpose of caring for the infirm. To the contrary, research and medical care are closely intertwined. Medical advances are only possible because of the pioneering efforts of scientists and physicians.

Yet what has any of this to do with Mass General's conduct here? The jury never considered Mass General's charitable immunity defense. Indeed, all the parties and the Court kept deferring consideration of the charitable immunity defense until "later," believing that surely it could be resolved as matter of law. Neither party objected to the Court's jury instructions which did not address charitable immunity. All parties elected to reserve resolution of this issue until post-trial. Compare Ramos v. Davis & Geck, Inc., 224 F.3d 30, 2000 WL 1177461, at *3 (1st Cir. 2000). Yet, even their post-verdict briefs are void

of any reference to this procedural conundrum. This issue, however, cannot be resolved as matter of law. Fact finding is required. What now?

Fortunately, the Federal Rules of Civil Procedure lend guidance. Rule 49(a) provides:

> The court shall give to the jury such explanation and instruction concerning the matter thus submitted as may be necessary to enable the jury to makes its findings upon each issue. If in so doing the court omits any issue of fact raised by the pleadings or by the evidence, each party waives a right to a trial by jury of the issue so omitted unless before the jury retires the party demands its submission to the jury. As to an issue omitted without such demand the court may make a finding . . . .

Fed. R. Civ. P. 49(a).[10] The First Circuit observed that when a party fails to request either a "special question" or an instruction submitting a particular theory to the jury, the "party makes a choice that has the associated consequence of almost certainly precluding the assertion after verdict of the omitted theory . . . ." Aetna Cas. Sur. Co. v. P & B Autobody, 43 F.3d 1546, 1555 (1st Cir. 1994). Here, the parties did not preclude the assertion of charitable immunity post-verdict. The parties,

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[10] The Court recognizes that this is an imperfect solution to a difficult procedural question. The current posture of this case does not fit neatly into any one rule. Rule 49 offers the best option, both in policy and language. Rule 51 also offers an alternative. See Fed. R. Civ. P. 51. Neither party objected to the Court's instructions to the jury which omitted any consideration of the affirmative defense of charitable immunity. As a result, a party cannot now assign error to the omission. The parties do not suggest the Court erred, however. Thus, the election policy undergirding Rule 49 seemed the more fitting choice, the parties apparently making no objection to the Court's consideration and determination of the factual issues in this instance.

specifically Mass General, reserved its right to assert the theory once the verdict was obtained. What was waived, however, is the right to have the issue of charitable immunity decided by the jury. By electing to withhold submission of the theory to the jury, the parties have waived the right to a jury trial on this issue. Thus, the Court will make the findings necessary to resolve this issue.

Relying upon the same evidence that the Court earlier ruled sufficient as matter of law for the jury to find Mass General vicariously liable, the Court independently finds it liable for the actions of Sweet. Moreover, the Court finds that during the treatment of both Heinrich's and Sienkewicz's decedents, Sweet had actual knowledge of the imprecision of the localization of the boron injections to the cancerous brain tissue and the related imprecision of the neutron radiation, with the result that unacceptably high degrees of radiation necrosis were occurring in these and other of his patients. In short, Sweet well knew during his care of these patients that his BNCT treatments were not helping them, and, in fact, were causing severe side effects unrelated to the progressive effect of the fatal brain tumors. He pressed ahead anyway, believing in complete good faith that such experimentation on dying patients held out hope for other cancer victims.[11] However praiseworthy his goal, his conduct with respect to the patients involved here was, as the jury found, negligent. While Mass General disagrees with these findings, they are amply warranted on the trial record.

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[11] The most poignant of Sweet's medical hubris is found in the testimony of Marie Denning, Eileen Sienkwicz's sister. She testified that she visited her sister in Mass General shortly before the latter's death. She found her sister struggling feebly against the nurses, begging them not to give her any more boron neutron injections. See Tr. of Denning Trial Test. at 15:18-17:12. Marie Denning went to see Dr. Sweet and asked him to discontinue the treatments. See id. at 17:13-18:2. His response was to say "Your sister's been through a lot and for the good of mankind . . . this will help." Id. at 17:23-24.

Vicarious negligence on the part of Mass General does not, however, strip it of its charitable immunity.

Moreover, Mass General points to the jury finding that held Sweet free from liability for any lack of informed consent. This jury finding is, of course, binding on this Court. Implicit in the jury finding is the view, necessarily adopted by this Court, that those of Sweet's patients that are involved here were kept fully apprized of Sweet's knowledge and proceeded voluntarily in light of it. The informed consent of the patients and their guardians, argues Mass General, ends any speculation that it was proceeding ultra vires with respect to them.

Had the federal government timely promulgated even the most rudimentary protocol for research experiments on human subjects, this Court would have a clear standard against which to measure the nature of the conduct of Sweet and Mass General. Massachusetts follows the salutary principle that even informed consent will not bar liability for a statutory violation. See Henry v. Mansfield Beauty Acad., Inc., 353 Mass. 507, 510-11, 233 N.E.2d 22 (1968) (Raymond S. Wilkins, C.J.).[12] Here, had the Atomic Energy Commission promulgated relevant regulations, they would have had the force of statutory law and Sweet could have violated them only at his (and Mass General's) peril. There is here, however, no relevant protocol to

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[12] Federal law is to the contrary, at least with respect to the reach of the Federal Arbitration Act. The cases are legion that one who agrees to arbitrate a dispute gives up all manner of constitutional, statutory, and procedural protections, see, e.g., Gilmer v. Interstate/Johnson Lane Corp., 500 U.S. 20, 35, 114 L. Ed. 2d 26, 111 S. Ct. 1647 (1991); MS Dealer Serv. Corp. v. Franklin, 177 F.3d 942, 949 (11th Cir. 1999); Design Strategy Corp. v. Nghiem, 14 F. Supp. 2d 298, 302 (S.D.N.Y. 1998), even when such "agreement" comes as the entry fee to a sweeping array of modern economic activity, see, e.g., Gilmer, 500 U.S. at 20; Rosenberg v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 170 F.3d 1, 17 (1st Cir. 1999).

which the Plaintiffs can point as having been violated by Sweet. The sad fact is that the Atomic Energy Commission ceded to the physicians involved the ability to establish whatever parameters they thought appropriate for experimentation on dying human patients. Even so, the jury finding of informed consent does not determine Mass General's liability here. Unlike assumption of the risk, informed consent has never operated as a defense to a claim of negligence in Massachusetts. This is reasonable. A patient who grants informed consent to a medical procedure assumes the risk inherent in the proper administration of that procedure; that patient does not assume the risk that the physician, as did Sweet here, would administer the boron-neutron doses negligently, well after any hoped-for therapeutic value was manifestly absent. In short, the jury findings of negligence and informed consent are neither inconsistent nor mutually exclusive.

While Mass General thus was negligent along with Sweet, the doctrine of charitable immunity will relieve it from liability so long as its conduct was "charitable."

It was not.

Simply calling human experiments "research" does not make them "charitable" no matter the good faith of the physicians and hospital involved. One need not invoke the specter of the war crime trials of twenty Nazi physicians to make the point. See Anthony Szczygiel, Beyond Informed Consent, 21 Ohio N.U. L. Rev. 171, 194 (1994). It is impossible to characterize the Tuskegee Syphilis Study as "charitable." See id. at 195. Nor can the injection of live cancer cells into twenty-two cancer-free, chronically mentally-ill patients without their or their guardians' knowledge or consent be defined as benevolent. See Hyman v. Jewish Chronic Disease Hosp., 21 A.D.2d 495, 251 N.Y.S.2d 818, 820 (N.Y.

App. Div. 1964), rev'd, 15 N.Y.2d 317, 258 N.Y.S.2d 397, 206 N.E.2d 338 (N.Y. 1965). Further, no matter how liberal a construction is given to "charitable purpose," it does not encompass radiation "treatment" of institutionalized, mentally-retarded children. In the late 40s and early 50s, these children were given radioactive iron or radioactive calcium to study their effects as part of a "nutritional study." See ACHRE Report, Chapter 7: The Studies at the Fernald School, available at (visited on Sept. 27, 2000) <http://tis-nt.eh.doe.gov/ohre/roadmap/achre/chap7-7.html>. The children were persuaded to participate in the experiment by being offered special treats like extra milk, occasional outings, and membership in a "Science Club." See id. The judgment of history rightly condemns this conduct. In hindsight, it's simply not "charitable" and the good faith of the misguided participants would not protect them under Massachusetts law.

Here, by negligently persisting with boron injections after all hope of extending the lives of his patients or alleviating their suffering had vanished, Sweet violated that cardinal principle of the Hippocratic oath, "First, do no harm." The negligent harm done by Sweet here and imputed to Mass General was in no sense "charitable." Mass General simply cannot cloak conduct violative of medical ethics with charitable immunity. The jury verdict must stand.

CONCLUSION

Defendants' Motion for Reduction of Jury Verdict is GRANTED. [docket no. 315]. The wrongful death statute in effect at the time the action arose, in 1961, is the correct statute. The statute of limitations was tolled. Mass General's Motion for Judgment as a Matter of Law on Charitable Immunity is DENIED. [docket no. 338]. Mass General is subject to the ordinary rules of liability.

SO ORDERED. WILLIAM G. YOUNG
U.S. DISTRICT JUDGE
9/29/00

APPENDIX C

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

NO. 00-2553
NO. 00-2554
NO. 00-2555

EVELYN HEINRICH, ET AL, Plaintiffs, Appellees,
v.
WILLIAM H. SWEET, M.D., Defendant, Appellant.

EVELYN HEINRICH, ET AL., Plaintiffs, Appellants,
v.
WILLIAM H. SWEET, M.D., ET AL., Defendants, Appellees.

EVELYN HEINRICH, ET AL., Plaintiffs, Appellees,
v.
MASSACHUSETTS GENERAL HOSPITAL, Defendant, Appellant.

November 14, 2002

ORDER OF COURT

RICHARD CUSHING CONOVAN, CLERK

The panel of judges that rendered the decision in this case having voted to deny the petition for rehearing and the suggestion for the holding of a rehearing en banc having been carefully considered by the judges of the Court in regular active

service and a majority of said judges not having voted to order that the appeal be heard or reheard by the Court en banc.

It is ordered that the petition for rehearing and the suggestion for rehearing en banc be denied.

After a review of the record, Judge Torruella is of the opinion that neither the facts nor the law support the panel's decision to vacate the jury's verdict. He therefore respectfully regrets the decision of the court to deny en banc review.

ENTERED: Richard Cushing Donovan, Clerk
11-14-02
Date

APPENDIX D

ARTICLE VII

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

U.S. CONST., amend. VII.

APPENDIX E

Rule 50. Judgment as a Matter of Law in Jury Trials; Alternative Motion for New Trial; Conditional Rulings

(a) Judgment as a Matter of Law.

(1) If during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.

(2) Motions for judgment as a matter of law may be made at any time before submission of the case to the jury. Such a motion shall specify the judgment sought and the law and the facts on which the moving party is entitled to the judgment.

(b) Renewing Motion for Judgment After Trial; Alternative Motion for New Trial. If, for any reason, the court does not grant a motion for judgment as a matter of law made at the close of all the evidence, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. The movant may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of judgment--and may alternatively request a new trial or join a motion for a new trial under Rule 59. In ruling on a renewed motion, the court may:

(1) if a verdict was returned:

(A) allow the judgment to stand,

(B) order a new trial, or

(C) direct entry of judgment as a matter of law; or

(2) if no verdict was returned:

(A) order a new trial, or

(B) direct entry of judgment as a matter of law.

(c) Granting Renewed Motion for Judgment as a Matter of Law; Conditional Rulings; New Trial Motion.

(1) If the renewed motion for judgment as a matter of law is granted, the court shall also rule on the motion for a new trial, if any, by determining whether it should be granted if the judgment is thereafter vacated or reversed, and shall specify the grounds for granting or denying the motion for the new trial. If the motion for a new trial is thus conditionally granted, the order thereon does not affect the finality of the judgment. In case the motion for a new trial has been conditionally granted and the judgment is reversed on appeal, the new trial shall proceed unless the appellate court has otherwise ordered. In case the motion for a new trial has been conditionally denied, the appellee on appeal may assert error in that denial; and if the judgment is reversed on appeal, subsequent proceedings shall be in accordance with the order of the appellate court.

(2) Any motion for a new trial under Rule 59 by a party against whom judgment as a matter of law is rendered shall be filed no later than 10 days after entry of the judgment.

(d) Same: Denial of Motion for Judgment as a Matter of Law. If the motion for judgment as a matter of law is denied, the party who prevailed on that motion may, as appellee, assert grounds entitling the party to a new trial in the event the appellate court concludes that the trial court erred in denying the motion for judgment. If the appellate court reverses the judgment, nothing in this rule precludes it from determining that the appellee is entitled to a new trial, or from directing the trial court to determine whether a new trial shall be granted.

APPENDIX F

Rule 51. Instructions to Jury: Objection

At the close of the evidence or at such earlier time during the trial as the court reasonably directs, any party may file written requests that the court instruct the jury on the law as set forth in the requests. The court shall inform counsel of its proposed action upon the requests prior to their arguments to the jury. The court, at its election, may instruct the jury before or after argument, or both. No party may assign as error the giving or the failure to give an instruction unless that party objects thereto before the jury retires to consider its verdict, stating distinctly the matter objected to and the grounds of the objection. Opportunity shall be given to make the objection out of the hearing of the jury.

No. 02-1251

Supreme Court, U.S.
APR 25 2003
CLERK

IN THE

Supreme Court of the United States

EVELYN HEINRICH and HENRY M. SIENKEWICZ, JR.,
Petitioners,

v.

ELIZABETH DUTTON SWEET and FREDERICK H. GREIN, JR., Representatives of the Estate of WILLIAM H. SWEET, M.D., and MASSACHUSETTS GENERAL HOSPITAL,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENTS ELIZABETH DUTTON SWEET AND FREDERICK H. GREIN, JR., REPRESENTATIVES OF THE ESTATE OF WILLIAM H. SWEET, M.D.

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QUESTION PRESENTED FOR REVIEW

When stripped of argumentation and reduced to its essence, the question presented by the petitioners is whether the court of appeals misapplied a rule of law that it properly stated — the standard of appellate review dictated by Fed. R. Civ. P. 50 and the case law pertinent to it — when it held that the evidence at trial was insufficient for a reasonable jury to find in the petitioners' favor on their negligence and wrongful death claims against William H. Sweet, M.D. and Massachusetts General Hospital.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-35a) is reported at 308 F.3d 48. The district court issued five published opinions, reported at: (1) 44 F. Supp. 2d 408; (2) 49 F. Supp. 2d 27; (3) 62 F. Supp. 2d 282; (4) 83 F. Supp. 2d 214; and (5) 118 F. Supp. 2d 73 (Pet. App. 36a-72a).

STATEMENT OF THE CASE

A. The Medical Background.

This action was brought in 1995 by the survivors of two patients who died in 1961. Both suffered from glioblastoma multiforme, which is the commonest, and the deadliest, form of brain cancer. It is especially difficult to treat surgically because the tumor consists of a main tumor mass with fingerlets of cancer cells infiltrating the healthy brain tissue surrounding the main tumor. These fingerlets are well vascularized and multiply rapidly. JA 3938. Untreated, or treated with conventional therapy (craniotomy and radiation), glioblastomas are invariably fatal. Survival times are measured in months. JA 4153.

The decedents were participants in clinical trials of a treatment called boron neutron capture therapy ("BNCT"). The theory of BNCT evolved from the discovery that two distinct moieties, boron-10 (B^{10}) and thermal neutrons, each innocuous by itself in the doses used, would interact to produce a highly localized nuclear reaction. JA 2828-29. BNCT involves the injection of a compound containing boron-10 into the blood-stream supplying the brain, where it is taken up by tumor tissue but not by normal brain tissue. JA 2939-40. The tumor is then exposed to a slow neutron beam generated by a nuclear reactor. Slow neutrons are low in energy and do not normally harm tissue. JA 2831. When the neutron beam encounters a boron-10 atom, however, the atom "captures" an additional neutron. The nucleus is de-stabilized and immediately undergoes a fission reaction, destroying the surrounding cells. JA 2956. The mass and the charges of the particles created by the fission preclude them

from traveling more than the approximate diameter of a single cell. JA 2829, 2939, 2956-60. In theory, then, BNCT is a way to deliver highly energetic and highly localized radiation that destroys tumor cells while sparing normal brain tissue. JA 2828-31, 2939, 2956-60, 3897. Whereas tumor tissue is some 10 to 20% more sensitive to conventional radiation than healthy tissue, BNCT promised an advantage of some 400%. JA 1858-59, 1984-87.

BNCT was a lifelong research interest of William H. Sweet, M.D., the late chief of neurosurgery at Massachusetts General Hospital ("MGH"). JA 1813. William Herbert Sweet was born on February 10, 1910 in Washington State. JA 1807. He was about 50 years old at the time that he treated the petitioners' decedents, Eileen Sienkewicz and George Heinrich. He was 85 years old when plaintiffs filed suit in 1995, and was almost 90 years old when the case was tried in September 1999. By that time, his mental faculties had declined to the point that he could not testify, a fact of which the trial judge refused to apprise the jury. JA 500-02, 1121, 1814-15. Dr. Sweet died on January 22, 2001. JA 0043.

Dr. Sweet first participated in BNCT trials at Brookhaven National Laboratories in 1950-51, the results of which had been disappointing.[1] While no patient suffered serious complications and about half the patients seemed to recover following BNCT, the recoveries proved short-lived, and all patients died of their cancers. JA 2969-71. Dr. Sweet and other researchers believed the reasons were that: (1) the radiation dose delivered by the Brookhaven reactor was too low to treat even shallow tumors; (2) the radiation was in the form of highly thermal neutrons, which have relatively low tissue penetration; and (3) an optimal boron compound remained to be found. *Id.*

---

1. The Complaint was amended to add claims on behalf of decedents Joseph Mayne and Walter Van Dyke, who participated in the Brookhaven BNCT trials. These claims were dismissed prior to trial, a decision that was not appealed.

A research reactor located at the Massachusetts Institute of Technology ("MIT") in Cambridge, Massachusetts, became operational in 1958. JA 4023-24. The MIT reactor was capable of delivering a much higher neutron flux, or flow rate, than the Brookhaven reactor, and was constructed with a fully functioning surgical operating facility directly below it. In anticipation of clinical trials of BNCT, MIT physicists worked on various aspects of the neutron beam, including methods for measuring the decrease in neutron flux as the neutrons passed through tissue and were "captured" by boron-10 atoms. Formulae were developed to predict, from boron concentration and neutron flux, the amount of radiation delivered to the tumor. JA 1992-95.

At MGH, meanwhile, Dr. Sweet's team undertook extensive animal studies to evaluate more than 145 boron compounds; the six compounds with the most promising results in animal studies were then tested at low doses in 200 human subjects to determine which achieved the best concentration in tumor with minimal toxicity. JA 1851, 2231-45, 2270-73, 2336-39, 3908-13, 3984-86. Dr. Sweet's team also built on the research of others, including quantitative studies of the effects of ionizing radiation on monkeys, rabbits, and mice; of the effects of slow neutrons on mice and swine; and of the destruction of animal tumors using BNCT. JA 3901-02.

By 1960, there had been various modifications to BNCT which appeared to address the problems encountered in the Brookhaven trials. For the first time, Dr. Sweet would have the use of a reactor capable of delivering a high enough neutron flux. Several promising boron compounds — one extremely so — had been developed and tested, and appeared ready for use. JA 2972-75. A new series of clinical trials of BNCT was thus set to begin at the MIT reactor. In each case, a conventional craniotomy would be performed to establish the diagnosis and to remove as much tumor mass as possible. JA 3914. An interval of several weeks would then be allowed for the blood-brain barrier in surrounding healthy tissue to rebuild prior to BNCT treatment. *Id.* The operating room below the MIT reactor would

permit a follow-up craniotomy at the time of irradiation so that neutron radiation could be delivered directly to the tumor.

Mrs. Sienkewicz was Patient No. 1 in the MIT series. JA 2866, 2977, 3916, 6371. In June 1960, she was diagnosed with a glioblastoma multiforme. JA 6368-69. She was discharged from MGH following a conventional craniotomy, but became increasingly lethargic and depressed over the summer, suffered from nervousness and insomnia, and began fumbling for words. JA 6370, 6376-80. According to her medical records, Mrs. Sienkewicz reported that she "just [sat] around at home feeling that everything is hopeless," "[felt] that life [was] no longer worth living," and that "thoughts of death [were] with her all the time." JA 6370, 6377, 6379.

Mrs. Sienkewicz was readmitted to MGH on November 13, 1960, and underwent BNCT on November 15. JA 6365. Her lethargy worsened at first, but two days later she began to improve until she became as alert and responsive as she had been preoperatively. JA 6370-71. Her depression continued, however, and became worse after her discharge on December 3. JA 6375. Electroshock therapy the first week of January produced marked improvement in her mood ("very cheerful, and up and about doing her housework at home"). JA 6372.

In late February 1961, she developed a sudden left-sided headache, weakness of the right limbs, increased difficulty with speech, and double vision, and so was hospitalized at MGH again. Her speech improved spontaneously and she was "alert and pleasant" the following day. She was discharged on March 4, 1961 with minimal aphasia (language impairment) and "no definite diagnosis of recurrent tumor." JA 6372.

Over the summer of 1961, Mrs. Sienkewicz became increasingly disoriented, nervous, insomniac, aphasic, and depressed. JA 6414. She was admitted to MGH in August 1961 because of nervousness, headaches, nausea and vomiting. A scan suggested recurrent tumor. JA 6365. In September 1961, she was again admitted to MGH because of continuing

headaches, lethargy, insomnia, aphasia, depression, and a suicide gesture. A scan showed a "definite abnormality" in the region of the tumor. She continued to deteriorate, eventually lapsing into a coma. She died on October 31, 1961, eighteen months from her diagnosis and nearly a year after undergoing BNCT. JA 6365-66.

George Heinrich, age 35, was Patient No. 6 in the series. JA 2882. He had been diagnosed with a glioblastoma multiforme following a craniotomy on October 25, 1960. JA 6082, 6305. Despite radiation treatments, the tumor recurred within a few weeks, with bulging evident at the surgical site. JA 6097, 6123, 6127, 6305. He was readmitted for further evaluation from December 4 to 8, electing to go home for the holidays and come back for a second surgery. JA 6095, 6129-30. He returned to MGH on December 11, however, with increased swelling and a blind spot in his left eye. JA 6129-30. On December 15 his craniotomy site was reopened and a massively recurrent tumor excised. JA 6305. He went home feeling well on December 24 (JA 6128), but by the morning of January 2, 1961 the surgical wound became separated and inflamed and he was admitted for further evaluation. A staph infection was treated with antibiotics and subsided. JA 6305-06.

Mr. Heinrich received BNCT at MIT on January 18, 1961. JA 2882. At that point in time, Eileen Sienkewicz had made a good recovery following her BNCT; her tumor had not reappeared, and her depression had resolved.[2]

Around February 10, 1961, Mr. Heinrich became increasingly lethargic, aphasic, and nonresponsive. JA 6306.

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2. Of the four intervening BNCT patients: Patient 2 was not irradiated because the tumor was too far advanced; Patient 3 (BNCT 11/30/60) had made a satisfactory recovery but would die of meningitis six weeks after treatment; Patient 4 (BNCT 12/30/60, a melanoma patient) had recurrences in other areas of the body, and would die after five months; and Patient 5 (BNCT 1/6/61) showed no apparent improvement and died at two months. JA 2977, 3916.

A brain scan on April 11 showed a definite abnormality in the region of his tumor, and by early May the surgical site was tense again. *Id.* His downward course continued, and he was transferred to a nursing home on May 15, 1961, where he died twelve days later. JA 6307, 6314.

Sixteen patients received BNCT (one patient twice) in the initial trial at the MIT reactor between November 1960 and August 1961.[3] Initial results — notably, Mrs. Sienkewicz's "strikingly improved" condition after BNCT, and her long survival time — induced "cheerful optimism" for awhile among Dr. Sweet and his team. JA 3915. As time went on, however, the results grew steadily more discouraging, with average survival times roughly the same as with conventional therapies then available. Half of the patients died within six months after irradiation, and none lived a full year. No one yet knew why. "Tentatively," Dr. Sweet concluded in October 1961, "we can say that we have not given enough radiation to tumor cells." JA 3986.

Much later, neuropathology provided some clues to the outcome. In a conference paper delivered in 1964 and published in 1972, the University of California's Dr. Arthur Asbury presented the findings of his microscopic analysis of brain tissue from fourteen of the MGH-MIT patients. In all cases studied, the cause of death was "cerebral in nature": extensive radiation necrosis in nine (including Sienkewicz and Heinrich); recurrent tumor in two; combined recurrence and radiation necrosis in one; and one case each of intracranial hemorrhage and acute

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3. A second series began soon after, using a newly developed boron compound, which appeared to offer significant advantages: it concentrated well in tumor tissue, and its low toxicity permitted it to be administered in higher doses than previous compounds. Unexpectedly, the first two patients worsened after BNCT. The first lived just three months, and the second died in two weeks, apparently of radiation effects. JA 3915, 3918. Improved dosimetry revealed that Patient 2 had received twice the radiation expected. Dr. Sweet halted this trial after just two patients. JA 3915.

bacterial meningitis. JA 0844, 2832-38, 2851-52. Particularly striking were the findings of inflammation and eventual scarring and thickening of the walls of cerebral blood vessels of all sizes. JA 2833-38, 2849-52. To the authors of the published paper — Dr. Sweet among them — this "raise[d] the suspicion that boron may have sequestered in vessel walls, resulting in selectively high doses of radiation to those structures." JA 2850. This was the first the Sweet team knew of or suspected this problem. JA 1903-04, 2282-83, 2286-88, 2349.

In a frank self-assessment published in 1964, Dr. Sweet and his team described the 1960-61 trials as "singularly unsuccessful," and attributed their failure to "four deficiencies": failure to appreciate how boron acted in the body, and "specifically . . . the need to clear it from the cerebral bloodstream"; inadequate knowledge of boron chemistry; inadequate methods for optimizing the shape of the neutron beam; and the lack of the equipment needed for accurate measurements of neutron radiation dose. JA 2935.

Though he remained a passionately interested observer, the 1960-61 series were Dr. Sweet's last clinical trials of BNCT. Researchers at other locales, however, built on his work, with some successes. Most notable was Dr. Hiroshi Hatanaka, who had become interested in BNCT while working with Dr. Sweet as a post-doctoral student at MGH. In clinical trials in Japan between 1968 and 1989, Dr. Hatanaka's team achieved five-year survival rates with BNCT that were far greater than with conventional therapy: 19% overall, and 58% in patients with tumors 6 cm deep or less. JA 0824-25, 2961, 2982-92. The defendants offered, but the district court excluded, additional evidence of ongoing work with BNCT. JA 1076-79, 1082-83, 2342-45.

B. The Litigation.

In 1995, representatives of the estates of George Heinrich and Eileen Sienkewicz filed an eleven-count class action complaint in the United States District Court for the Eastern

District of New York, asserting claims of: (i) violation of constitutional and civil rights under the Bivens rule; (ii) civil fraud; (iii) battery; (iv) intentional infliction of emotional distress; (v) strict liability for inherently dangerous activities; (vi) personal injury caused by exposure to toxic substances; (vii) absence of informed consent; (viii) wrongful death; (ix) "civil responsibility for crimes against humanity;" (x) negligence; and (xi) negligent misrepresentation. The case eventually found its way to Chief Judge William G. Young of the United States District Court for the District of Massachusetts. Judge Young issued three lengthy, published opinions prior to trial dealing with various aspects of this complex case.[4]

The jury heard evidence over fourteen days beginning on September 10, 1999. During the trial, the plaintiffs called two

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4. In *Heinrich ex rel. Heinrich v. Sweet*, 44 F. Supp. 2d 408 (D. Mass. 1999) ("*Heinrich I*"), the district court denied the United States' motion to dismiss, holding that the plaintiffs' administrative claims were timely. In *Heinrich ex rel. Heinrich v. Sweet*, 49 F. Supp. 2d 27 (D. Mass. 1999) ("*Heinrich II*"), the district court ruled that in view of the permissive transfer from the Eastern District of New York, New York law would govern the state-law claims, and ordered further briefing on New York statutes of limitations. The district court also held that the federal claims were timely; and dismissed on substantive grounds the counts for battery, intentional infliction of emotional distress, strict liability, toxic substances, and crimes against humanity. In *Heinrich ex rel. Heinrich v. Sweet*, 62 F. Supp. 2d 282 (D. Mass. 1999) ("*Heinrich III*"), the court held that under the Price-Anderson Act, 42 U.S.C. §§ 2014(q) and (hh) and 2210(n)(2) and (s), each plaintiff's BNCT claim was subject to the limitations rules and substantive law of the state where the "nuclear incident" — radiation injury at a licensed nuclear reactor — occurred. It thus dismissed as untimely all claims except those premised on BNCT in Massachusetts (all claims governed by New York law were time-barred). The district court deemed Heinrich's and Sienkewicz's decades-old BNCT claims timely because in the court's view, "Massachusetts imposes a fiduciary duty on doctors to disclose known possible causes of action to patients," and because the court applied retroactively a 1989 statute enacting a discovery rule for wrongful death actions.

expert witnesses whose testimony was relevant to the negligence and wrongful death counts: Larry Junck, a neurologist and neuro-oncologist, and Michael Grodin, a medical ethicist.

Dr. Junck based his opinions on documents that he received exclusively from plaintiffs' counsel, including patient charts and medical literature. JA 982, 1084-86. In his view, the defendants acted "inappropriately and irresponsibly" in administering boron injections and BNCT to Eileen Sienkewicz and George Heinrich. JA 985-86. He was not asked, and did not say, whether the defendants deviated from the applicable standard of care. Moreover, he admitted that he could not say whether BNCT hastened the death of either patient (i.e., that either died sooner from the effects of BNCT than (s)he would have if treated conventionally or not at all); he characterized any attempt to opine on that point as "hypothetical," with "no basis." JA 1116, 1129.

Dr. Grodin talked mostly about informed consent, which the plaintiffs claimed Dr. Sweet had failed to obtain from his patients; the jury ultimately found for Dr. Sweet and MGH on that claim. JA 177-79. Dr. Grodin also testified that a physician or institutional review board considering human trials should engage in a risk/benefit analysis, and that, in his view, the risks of BNCT outweighed the potential benefits. JA 1376-83, 2407-08. Like Dr. Junck, Dr. Grodin did not testify that BNCT violated any standard of care, either in 1961 or presently, of the average qualified neurosurgeon or of anyone else engaged in clinical trials.

There were three defense experts: Drs. Laws and Fager, both neurosurgeons, and Dr. Koski, an anesthesiologist who at the time of trial was Director of Human Research Affairs for Partners Healthcare System. They testified that Dr. Sweet's conduct in the BNCT trials complied with the standard of care for the average qualified neurosurgeon in 1960-61 and with the prevailing norms for human clinical trials. JA 2130-35, 2197-98, 2363-67. Dr. Sweet did not testify, as his age (89) and medical

condition had rendered him incompetent. He died on January 22, 2001, shortly after his 91st birthday.

On defense motions for judgment as a matter of law, the court dismissed the fraud and negligent misrepresentation claims, and sent to the jury the claims for absence of informed consent, wrongful death, and negligence. The jury returned a verdict for MIT on all counts; for Dr. Sweet and MGH on the informed consent count; but for the plaintiffs against Dr. Sweet and MGH on the negligence and wrongful death counts. It awarded compensatory and punitive damages.

Dr. Sweet and MGH filed a motion for new trial, a renewed motion for judgment as a matter of law, and a motion for reduction of the jury award. In *Heinrich ex rel. Heinrich v. Sweet*, 118 F. Supp. 2d 73 (D. Mass. 2000) ("*Heinrich V*"), the district court granted the motions for reduction of the jury award, on the ground that the court should have applied the Massachusetts wrongful death statute as in effect in 1960-61, when the treatment and deaths occurred, rather than the 1995 version. This had the effect of reducing the damages award by nearly ninety percent. The court otherwise denied the post-trial motions. Dr. Sweet, MGH and the plaintiffs all appealed.

In an opinion issued on August 27, 2002, the Court of Appeals for the First Circuit vacated the judgment altogether, holding that judgment should have been entered for Dr. Sweet and MGH as a matter of law because plaintiffs had failed to present legally sufficient evidence to support their negligence and wrongful death claims: "Conclusory opinions, unattached to predicate evidence of existing standards, cannot fairly fill the void." Pet. App. 35a.

REASONS FOR DENYING THE PETITION

A. The Question Presented By The Petitioners Is Simply Whether The Court Of Appeals Correctly Applied A Rule Of Law That It Properly Stated, And As Such Does Not Warrant This Court's Review.

Petitioners have made no sincere attempt to explain why this case merits the Court's attention. They argue throughout their brief that the court of appeals deprived them of their right to a jury trial, but they do not explain how this case differs in principle from any of the myriad other cases in which federal trial and appeals courts measure the evidence presented to juries by the legal sufficiency standard of Fed. R. Civ. P. 50(a)(1). The reason that the petitioners fail to explain is that no such difference exists, and their true complaint is fact-based and case-specific.

"The Supreme Court is not, and never has been, primarily concerned with the correction of errors in lower court decisions." *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting) (*quoting* Address of Chief Justice Vinson before the American Bar Association, Sept. 7, 1949, as quoted in R. Stern & E. Gressman, Supreme Court Practice 258 (5th ed. 1978)). Its function, rather, is "to resolve conflicts of opinion on federal questions that have arisen among lower courts, to pass upon questions of wide import under the Constitution, laws, and treaties of the United States, and to exercise supervisory power over the lower federal courts." *Id.*

The court of appeals' decision does not conflict with any decision of this Court or of any other court of appeals. The decision at issue has no "importance to the public as distinguished from that of the parties." *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387 (1923). Moreover, petitioners' assertion that the court of appeals misstated the applicable standard is not true.

Petitioners acknowledge, as they must, that "[a] petition for a writ of certiorari is rarely granted when the asserted error

consists of erroneous factual findings or the misapplication of a properly stated rule of law." S. Ct. R. 10. *See* Pet. Br. at 6. They have attempted to overcome this considerable obstacle by claiming that the court of appeals has announced a new standard for appellate review of the trial court's denial of a motion for judgment as a matter of law. Pet. Br. at 6-7.

The fact of the matter is that the court of appeals accurately and succinctly described the law governing its role:

> We review de novo a district court's denial of a Rule 50 motion for judgment as a matter of law. But "our review is weighted toward preservation of the jury verdict," *Rodowicz*, 279 F.3d at 41, and "we must affirm unless the evidence was 'so strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them," *Walton v. Nalco Chem. Co.*, 272 F.3d 13, 23 (1st Cir. 2001) (*quoting Negron v. Caleb Brett U.S.A., Inc.*, 212 F.3d 666, 668 (1st Cir. 2000)).

Pet. App. 14a.

Petitioners charge that this description "is at odds with the teachings of this Court, the other circuits and the Commonwealth of Massachusetts," and allegedly leaves the court of appeals free to ignore evidence and "substitute its own conclusions for those of the jury." Pet. Br. at 7. That claim is demonstrably false. The court of appeals broke no new ground in this case; the standard it followed is well-settled and entirely consistent with this Court's decisions.

One of the cases that the court of appeals cited in the present case as authority for the applicable standard was *Walton v. Nalco Chemical Co.*, 272 F.3d 13 (1st Cir. 2001). In *Walton*, the court stated (in addition to the language quoted in the present case, as set forth above):

> Judgments entered as a matter of law are reviewed *de novo*, and will be affirmed "only if, after

> scrutinizing the proof and inferences derivable therefrom in the light most hospitable to [the plaintiff], we determine that a reasonable factfinder could have reached but one conclusion: that [the defendant] w[as] entitled to judgment."

Walton, 272 F.3d at 18, *quoting Fleet National Bank v. Anchor Media Television, Inc.*, 45 F.3d 546, 552 (1st Cir. 1995). That language is indistinguishable in meaning from the language that the petitioners themselves urged upon the court of appeals as the correct articulation of the standard it should apply in its review: "The district court may grant a motion for judgment notwithstanding the verdict only upon its determination that the evidence could lead a reasonable person to only one conclusion." *Plaintiffs-Appellees' Consolidated Brief in Opposition to Briefs of Defendants-Appellants William H. Sweet, M.D. and Massachusetts General Hospital*, at 4-5, *Heinrich ex rel. Heinrich v. Sweet*, 308 F.3d 48 (1st Cir. 2002), *quoting Nydam v. Lennerton*, 948 F.2d 808, 810 (1st Cir. 1991). Saying that the jury's verdict could only be upended if the evidence was so "'strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them,'" as the court of appeals did here, is no different. What petitioners are now engaging in is "little more than semantic gamesmanship, rooted in a faulty premise." *Veranda Beach Club Ltd. v. Western Surety Co.*, 936 F.2d 1364, 1382 (1st Cir. 1991).

In *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133 (2000), this Court observed that "in entertaining a motion for judgment as a matter of law, the court should review all of the evidence in the record." *Reeves*, 530 U.S. at 150. Petitioners contend that because the court of appeals did not include a repetition of that well-known directive, the court failed to heed it. Silent the court might have been, but an examination of its thorough opinion compels the conclusion that it *did* consider all of the evidence. The court found, for instance, that "[t]here is *no evidence at all* in the record that BNCT hastened decedents' deaths." Pet. App. 17a (emphasis added). Even a casual reading

of the court's opinion reveals that the court thoroughly examined the evidence that petitioners proffered in support of their claims, and found it lacking. *See* Pet. App. 23a-30a.

Petitioners also claim that the court of appeals' recitation of the standard of review was "silent" about its obligation to defer to inferences the jury could have made in their favor. Pet. Br. at 11. They argue, for instance, that the jury was free to *infer* that BNCT hastened the decedents' deaths in spite of their own expert's testimony that it was impossible to tell.[5] The court of appeals said it best:

> [I]n a medical malpractice case in which plaintiff argues that the treatment, not the terminal disease, hastened the death, and all of the expert testimony is that it *cannot* be said that the treatment hastened the death, a jury is *not* free to reach a contrary conclusion. Whether such a treatment ultimately hastened a patient's death is not a topic of common experience; it requires expert testimony.

Pet. App. 16a-17a (emphasis added).[6]

B. The Court Of Appeals Correctly Applied The Proper Rule Of Law In Finding That Petitioners Failed To Present Legally Sufficient Evidence In Support Of Their Claims.

1. Petitioners Were Required, But Failed, To Present Expert Testimony Establishing That Dr. Sweet Breached The Applicable Standard Of Care.

In Massachusetts, the standard for medical malpractice liability is firmly established:

> The proper standard is whether the physician, if a general practitioner, has exercised the degree of care

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5. Pet. Br. at 22.

6. Petitioners also contend that they were not required to prove that BNCT hastened their decedents' deaths. This is discussed more fully below.

> and skill of the average qualified practitioner, taking into account the advances in the profession. In applying this standard it is permissible to consider the medical resources available to the physician as one circumstance in determining the skill and care required. Under this standard some allowance is thus made for the type of community in which the physician carries on his practice.
>
> One holding himself out as a specialist should be held to the standard of care and skill of the average member of the profession practicing the specialty, taking into account the advances in the profession. And, as in the case of the general practitioner, it is permissible to consider the medical resources available to him.

Brune v. Belinkoff, 235 N.E.2d 793, 798 (Mass. 1968) (citations omitted). "Taking into account the advances in the profession" means that the physician's conduct must be measured against the standard of care prevalent at the time of the alleged malpractice. *See, e.g., Haggerty v. McCarthy*, 181 N.E.2d 562, 565-66 (Mass. 1962); *Shu v. Eisenklam*, 585 N.E.2d 757, 759 (Mass. App. Ct.), *review denied*, 590 N.E.2d 195 (Mass. 1992) ("the standard of care of an average pediatrician in 1984"); *Albee v. Glesmann*, 503 N.E.2d 677, 679 (Mass. App. Ct.), *review denied*, 507 N.E.2d 1056 (Mass. 1987) ("[Y]ou are to look to the standard of care and skill in 1979, not the standard of care and skill in May, 1985").

For the jury to assess whether the defendants possessed the requisite knowledge of nuclear physics, chemistry, and medicine to proceed with innovative brain tumor therapy according to the standards prevalent in 1961 required expert testimony as to what those standards were and how the defendants' conduct deviated from them, if at all. "It is only in exceptional cases that a jury instructed by common knowledge and experience may without the aid of expert medical opinion determine

whether the conduct of a physician toward a patient is violative of the special duty which the law imposes as a consequence of this particular relationship." *Forlano v. Hughes*, 471 N.E.2d 1315, 1319 (Mass. 1984) (citation omitted). Were this a case of a surgeon leaving a foreign object in the patient, for example, the jury's "common knowledge and experience" could suffice. *Haggerty*, 181 N.E.2d at 565.

As the court of appeals found, the insufficiency of the plaintiffs' expert testimony on these points was fatal to their negligence and wrongful death claims.[7] The court of appeals did not review the admissibility of any expert testimony, as petitioners contend, and it said so expressly: "For purposes of this appeal, we assume that the district court did not abuse its discretion in qualifying any of the medical experts to testify, including Dr. Junck and Dr. Grodin." Pet. App. 23a. It found, rather, that in the case of both Dr. Junck and Dr. Grodin, the testimony

> was not tied to the time period in question, it did not state the standard of care or that Sweet had violated the standard of care, and it depended heavily on information about BNCT that became available to Dr. Sweet and his team only after the completion and analysis of the trials.

Pet. App. 26a-27a.

Dr. Junck expressed his opinions in strictly personal terms, untethered to any standard of care (let alone the relevant, 1961 standard). Calling a course of treatment "irresponsible," "inappropriate," and the like, as Dr. Junck did, does not establish a departure from the requisite standard of care, particularly where that standard was so far removed — in time and in subject matter — from the experience of the testifying expert that it cannot be said to have been "implicit" in his opinions. Dr. Junck's research into the state of the art of clinical trials in neurosurgery in 1961,

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7. The court of appeals summarized the shortcomings in plaintiffs' standard of care evidence at Pet. App. 34a.

which formed the basis for his opinion that Dr. Sweet's conduct was "inappropriate and irresponsible," consisted of reading medical journal articles about BNCT provided him by plaintiffs' counsel — a methodology he conceded he would not consider adequate for his own research. There was no indication that he did any research into the professional standards of the day governing clinical trials.[8] Dr. Grodin said nothing on the subject of standards in 1960-61 at all.

Petitioners' hyperbolic description of the results of the clinical trials as "horrific" and excoriation of the court of appeals' decision as "indefensible moral error" ignores the fact that clinical trials are an indispensable part of medical research. They claim (at page 16 of their Petition) that the jury should be permitted to infer that the standard of care had been breached simply because the BNCT team later realized that they had failed to fully appreciate how boron would act in the body. To permit such a leap, without the guidance of expert testimony, would be tantamount to ruling that the failure of new treatment modalities to cure those otherwise incurably ill patients who agree to participate in a clinical trial constitutes *per se* negligence.

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8. Petitioners suggest that the court of appeals took a narrow view of the applicable standard of care as that governing "standard treatment within the specialty of neurosurgery," without reference to clinical trials. Pet. Br. at 19. To the contrary, the court of appeals observed that "the determination of the standard of care owed by Dr. Sweet to the decedents must be influenced by . . . the fact that in treating the decedents he was also conducting medical research for a new treatment." Pet. App. 21a. The court recounted in detail Dr. Koski's testimony describing the painstaking scientific review process to which Dr. Sweet's proposal to conduct BNCT trials was subjected before it was approved by MGH and MIT. According to the court, "[a]pproval by these various committees is very compelling evidence to show that the BNCT trials complied with the prevalent standard of care at the time." Pet. App. 30a-31a.

It is quite apparent from the court's thorough discussion of the expert testimony that Dr. Sweet offered during his portion of the case that the court of appeals did not "limit[] its review to evidence received in Plaintiffs' case-in-chief," as petitioners complain. Pet. Br. at 27.

2. The Court Of Appeals Correctly Found No Admissions Or Other Legally Sufficient Evidence To Support A Finding Of Negligence.

Petitioners make much of "admissions" and "concessions" they claim were made by Dr. Gordon Brownell, an MIT physicist, and Dr. Albert Soloway, a chemist, both of whom worked with Dr. Sweet on the BNCT trials, but neither of whom were parties to the litigation.[9]

In all but the most exceptional cases, a doctor's breach of the standard of care must be established through expert testimony. *Forlano*, 471 N.E.2d at 1319. In some cases, the jury may also be aided by "evidentiary admission[s], which, if believed, [are] independently sufficient to justify a finding of negligence. . . ." *Collins v. Baron*, 467 N.E.2d 171, 174 (Mass. 1984). Petitioners now argue that even if their experts failed to carry them across the bar, Dr. Sweet's negligence might have been established by certain "admissions." "Testimony concerning conclusory admissions by a malpractice defendant may suffice to sustain a jury's finding of negligence if, from the admission, the jury 'could infer an acknowledgement of all the necessary elements of legal liability.'" *Collins*, 467 N.E.2d at 173 (*quoting Zimmerman v. Litvich*, 7 N.E.2d 437, 438 (Mass. 1937)). That did not happen.

Petitioners have cited no "admissions" attributable to Dr. Sweet that reasonably might be construed to support a finding of negligence. Nor do any of Dr. Sweet's writings, in which he forthrightly disclosed what he and the rest of the BNCT team had learned from the MIT BNCT trials, contain anything to suggest that he felt it had been negligent to proceed in the first place. To the contrary, the evidence was that the team members believed that they had found suitable boron compounds, that their estimates of the radiation dose would be accurate based on animal studies, and that the therapy held great promise.

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9. As discussed more fully below, petitioners have grossly mischaracterized Dr. Brownell's testimony.

- Dr. Soloway testified that Dr. Sweet's team believed that the compound used in the 1960-61 trial was suitable "based on the animal studies that had been done and the distribution studies in patients." JA 2270. Dr. Soloway added that although by 1964, test results had shown that Dr. Sweet's team did not have the right information, in 1960 and 1961, "[w]e thought we did." JA 2332. Plaintiffs' counsel successfully objected to the admission of any statements attributable to Dr. Sweet regarding his expectations for the boron compound's performance at the time the MIT trial was undertaken. *See* JA 2274-75, 2283.

- For his part, Dr. Brownell "believed that the theory and the measurements were entirely adequate at that time for the study to proceed." JA 1874. He had conducted studies to measure the neutron flux as it entered the brain, JA 1983-84, and felt that his physical studies regarding the radiation dose were accurate. JA 2000-01.

- As of October 1961, Dr. Sweet believed that the discouraging results of the MIT trial stemmed from the failure to deliver adequate radiation to tumor cells. JA 3986. Dr. Brownell testified that, as it turned out, the greatest limiting factor was the concentration of boron in blood vessels, but the team did not learn that until later. JA 1894, 2001. It was not until after the MIT clinical trial had ended that neuropathological tests, discussed in the Asbury article, revealed radiation necrosis in healthy cells. JA 0844, 2833-38.

Of course, it is wrong to attribute what was learned later — with the benefit of hindsight and microscopic examination of tissue samples — to the state of knowledge in 1960, when the trials were undertaken. As the court of appeals recognized, articles written after the fact "may sometimes contain probative information about the doctors' state of knowledge before they

begin a set a [sic] medical trials. This is not the case here. Instead, the articles' pertinent information was learned *after* the trials, once the doctors had an opportunity to study and analyze them." Pet. App. 24a. The court rejected petitioners' contention that Dr. Sweet's later writings could be construed as admissions of negligence:

> The plaintiffs also rely on articles and documents written by Dr. Sweet and others on his team after the BNCT trials conducted at MIT, to support the contention that the doctors themselves admitted to wrongdoing, and that these alleged admissions are sufficient to show that Dr. Sweet violated his duty of care to the plaintiffs. . . . No reasonable reader could view the articles, written after the BNCT trials at MIT ended, based on hindsight, and presented to colleagues in science and medicine for consideration, as admissions of wrongdoing. The articles, rather, are objective academic appraisals of the BNCT trials and their failures. The purpose of medical research and trials is to learn from them and improve medical treatments for diseases, including treatment for the subjects of the trials. There would surely be a chilling effect on research in the medical field and deterrence of important progress in medical treatments if doctors and scientists could not frankly assess the successes and failures of their studies in published academic articles so that others can build on their work and learn from it.

Pet. App. 29a-30a.

3. Petitioners Were Required, But Failed, To Proffer Any Evidence That BNCT Hastened The Decedents' Deaths.

Petitioners argue that they were not required to prove that the decedents' deaths were hastened in order to recover on their wrongful death claims. The trial judge instructed the jury,

however, that such proof was required, and the plaintiffs are bound by their agreement to that charge. *See Davis v. Rennie*, 264 F.3d 86, 100 (1st Cir. 2001), *cert. denied*, 535 U.S. 1053 (2002). In any event, the charge was correct.

In Massachusetts, it is the plaintiff's burden in a wrongful death case to show that a wrongful act or omission of the defendant "hastened the death of [the decedent], caused it to occur sooner than it would have happened otherwise." *Walker v. Gage*, 111 N.E. 766, 767 (Mass. 1916); *accord*, *Corriveau v. United States*, 832 F. Supp. 19, 23 (D. Mass. 1993); *Edwards v. Warwick*, 59 N.E.2d 194, 196 (Mass. 1945), and cases cited.

Plaintiffs' only expert testimony on medical causation came from Dr. Junck. He testified, based on the Asbury article, that the cause of death for both Sienkewicz and Heinrich was radiation necrosis caused by BNCT. When asked whether BNCT hastened the death of either, however, he could offer no information:

> Q. But you certainly cannot say that the administration of BNCT in any way hastened [Sienkewicz's] death; is that correct?
>
> A. That's correct.
>
> Q. And . . . you cannot say that the administration of the BNCT in any way hastened George Heinrich's death; is that correct?
>
> A. That's correct.

JA 1129. This was not, then, merely a case in which plaintiffs failed to produce expert testimony that death was hastened. It was worse: plaintiffs' own medical expert testified, affirmatively and without contradiction: "That would be just hypothetical and is just the kind of thing that I would have no basis for saying what would have happened had they not received BNCT and perhaps received some other treatment." JA 1116.

In the course of discussing the jury instructions with counsel prior to the charge, the judge described his intended instruction concerning the wrongful death claims:

> I will explain [that] if they find . . . negligence or lack of informed consent, they may but need not find wrongful death *because they would have to make the additional finding that the life was in fact shortened* as the proximate result of the conduct that they've either characterized as negligent, or from the activities as to which there was no informed consent.

JA 2525 (emphasis added). The next day, the court charged the jury as follows (applying the 1995 version of the Massachusetts wrongful death statute, MASS. GEN. LAWS c. 229, § 2):

> The wrongful death claim measures the damages by . . . the loss to the next of kin; the loss to the family; that loss . . . of companionship and care and the joy of having the person in the family relationship. . . .
>
> [T]hat means you have to shorten the life. . . . [H]ad there been no . . . procedure, the person would have gone downhill, and would eventually then have died of the disease, but because of the procedure they died earlier, then you can award damages to Mrs. Heinrich, and in the Sienkewicz case, to Mr. Sienkewicz. . . .
>
> [I]f the person would have died at the same time anyway, there's no damages under wrongful death, no damages at all.

JA 2610-11. Petitioners' counsel did not object, except to argue that punitive damages could still be awarded without a showing that death was hastened. The judge replied that he was "satisfied with the charge." JA 2619-20

That the district court instructed the jury on hastening in the context of damages, while the appeals court considered it as relating to proximate cause, is a distinction without a difference. The crucial point of the instruction was that if there is no showing that death was hastened, there can be "no damages under wrongful death, no damages at all." Even more to the point, petitioners are asking this Court to delve into the record to determine the correctness of the lower courts' treatment of a facet of state law with which this Court need not be concerned.

C. The Petition Is Rife With Misstatements.

Supreme Court Rule 15 requires that any misstatements in the petition be pointed out in this brief. In accordance with the Rule, and to set the record straight, it should be noted that petitioners have made the following misstatements:

1. On page 6, petitioners suggest that the court of appeals found that they had failed to prove that BNCT caused the decedents' deaths ("the court never mentioned" evidence "that Plaintiffs' deaths were caused by" BNCT). It is hardly surprising that the court of appeals would not bother to mention that radiation necrosis caused by BNCT was the medical cause of death, since that was not disputed in the papers before that court. *See Brief for Defendants-Appellants Elizabeth Dutton Sweet and Frederick H. Grein, Jr., Representatives of the Estate of William H. Sweet, M.D.*, at 17, *Heinrich ex rel. Heinrich v. Sweet*, 308 F.3d 48 (1st Cir. 2002) ("microscopic analysis of brain tissue from fourteen of the MGH-MIT patients" revealed that "the cause of death was 'cerebral in nature': extensive radiation necrosis in nine (including Sienkewicz and Heinrich)"). What the court of appeals found, rather, was that petitioners failed to proffer any evidence "*at all*" that BNCT *hastened* the death of either Heinrich or Sienkewicz. Pet. App. 17a.

2. On page 8, petitioners suggest that the court of appeals mischaracterized the results of the trials, stating that the court of appeals "ignored" evidence "that Defendants administered BNCT at the MIT reactor to eighteen patients, none of whom

survived. Post-mortem examination . . . revealed that nine died, not from cancer, but from radiation necrosis." There has been no dispute about any of these facts. Moreover, to say that the court of appeals ignored such evidence is a misstatement. As the court recognized: "That medical research at times produces results less than hoped for is to be expected. This does not logically lead to the conclusion that the research should not be undertaken." Pet. App. 24a.

3. Petitioners again take liberties with the evidence in footnote 6, on page 9 of their petition:

> In the interest of science, Dr. Sweet was determined to study the brains of the subjects. In the case of George Heinrich, who died at a nursing home, Sweet arrived at the funeral home just before the wake was to start, and persuaded Mrs. Heinrich to let him remove her husband's brain.

In contrast and contradiction to this lurid allegation, Mrs. Heinrich's testimony on the subject was that she did not speak to Dr. Sweet at the funeral home, but consented to an autopsy at the behest of her husband's family. JA 1710-11. It goes without saying that there is nothing diabolical about performing an autopsy when a terminal patient has participated in a clinical trial.

4. On pages 14-15 of their brief, petitioners grossly mischaracterize the evidence (primarily, the testimony of Drs. Soloway and Brownell) regarding what was known about the physics and chemistry of BNCT prior to the MIT trial.[10] It is true that full details concerning the precise biological effect of BNCT on humans were not known; indeed, one of the purposes for which the trials were undertaken was to determine exactly that, with the sincere hope that the answer would cure the patients in the study as well as future glioblastoma patients.

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10. In footnote 9, found on page 15, petitioners claim, apropos of nothing, that BNCT had been conducted on "dozens" of patients in the Brookhaven study. There were ten. JA 2949, 2951.

However, the integrity of petitioners' characterization of the evidence stops there.

Perhaps the most egregious misstatement of all is the following:

> Why did Defendants proceed even though they knew they had no basis to believe BNCT would do more good than harm? In Dr. Brownell's words because "We might as well go ahead and experiment on patients because we weren't going to get an answer to what we didn't know for decades to come."

Pet. Br. at 15. This statement is a fabrication. Dr. Brownell said nothing of the sort.[11]

5. In footnote 14, found on page 22 of their brief, petitioners deride the court of appeals for "ignor[ing]" what they claim constituted "evidence" that Mrs. Sienkewicz had a "variant of glioblastoma with a somewhat better prognosis than the other subjects" and was "without tumor at the time of the BNCT." The so-called "evidence" that they pressed upon the court of appeals consisted mostly of tortured interpretations of selected excerpts of Mrs. Sienkewicz's medical records. They argued below that, "It is a permissible inference that a candidate [Mrs. Sienkewicz] was chosen

11. The portion of the record cited by petitioners, JA 1905-07, is included in the Appendix to this brief, at App. 1a-4a. It is a portion of the transcript of Dr. Brownell's trial testimony under cross-examination by one of the plaintiffs' trial counsel, Mr. Freeman. As may be seen from that transcript excerpt, the only person who used words similar to those that the petitioners attribute to Dr. Brownell was Mr. Freeman, and even he has been misquoted. They formed part of a lengthy, convoluted preamble to a compound question that Mr. Freeman posed, which Dr. Brownell plainly did not adopt as his own testimony. *See* 125 word question beginning with the words, "Head of the nuclear engineering department," and witness's single word response, "No." App. 3a.

to be first who, because she didn't have glioblastoma multiforme, would survive longer, thus creating the aura of a successful experiment." The petitioners did not deign to explain to the court of appeals why such a monstrous inference would be "permissible." Moreover, it was a shabby tactic to argue for that inference, in light of the fact that plaintiffs/petitioners had renounced such an argument during the course of the trial:

> THE COURT: I'm not going to let the plaintiffs argue that Mrs. Sienkewicz, that this was all a terrible misdiagnosis and they killed her with their experiments and there really was nothing wrong with her.
>
> PLAINTIFFS' COUNSEL: No, we're not going to argue that.
>
> THE COURT: Because there's no expert testimony that would support that hypothesis. These people were, I am not going to emphasize it, but these people were terribly sick.

JA 2553-54; *see also* JA 2345. Plaintiffs abided by the trial court's ruling, did not appeal it, should not have argued the point to the court of appeals, and should not continue to make such defamatory arguments.

6. Finally, in support of their negligence argument, petitioners press upon this Court language in *Heinrich V*, in which the district judge stated:

> [T]he Court finds that during the treatment of both Heinrich's and Sienkewicz's decedents, Sweet had actual knowledge of the imprecision of the localization of the boron injections to the

> cancerous brain tissue and the related imprecision of the neutron radiation, with the result that unacceptably high degrees of radiation necrosis were occurring in these and others of his patients. In short, Sweet well knew during his care of his patients that his BNCT treatments were not helping them, and, in fact, were causing severe side effects unrelated to the progressive effect of the fatal brain tumors. He pressed ahead anyway, believing in complete good faith that such experimentation on dying patients held out hope for other cancer victims. However praiseworthy his goal, his conduct with respect to the patients involved here was, as the jury found, negligent.

118 F. Supp. 2d at 90. This finding, while dramatic, is completely unhistorical, and belied by the evidentiary record.

- Eileen Sienkewicz was Patient No. 1. Dr. Sweet could not have known "that his BNCT treatments were not helping" other patients, because none had been treated before Mrs. Sienkewicz. JA 2866, 2977, 3916.

- George Heinrich, treated just two months later, was Patient No. 6. Mrs. Sienkewicz was doing extraordinarily well then; all other patients were alive and showing mixed success. JA 2882, 2977, 3916.

- Eventually, autopsies disclosed radiation necrosis in many patients. When Mrs. Sienkewicz and Mr. Heinrich were treated, however, no autopsies had been performed, because no patient had died. JA 2866, 2977, 3916.

- There simply is not a shred of evidence that Dr. Sweet knew, or had any reason to know, that BNCT was not helping at least some of his patients until long after Mrs. Sienkewicz and Mr. Heinrich were treated. When he did conclude that his patients were doing no better than with conventional treatments, he stopped the BNCT. JA 3915.

The trial judge's description — "experimentation on dying patients" — and his lurid and irrelevant references to "the Tuskeegee Syphilis Study" and "the war crime trials of twenty Nazi physicians," *Heinrich V*, 118 F. Supp. 2d at 91, were thus wholly unsupported in the record. They also were defamatory of the reputation of a pioneer of American medicine who, because of his failing health nearly four decades after the events in issue, was unable to speak in his own defense.

CONCLUSION

The court of appeals applied the correct standard to the district court's denial of the defendants' motions for judgment as a matter of law, and applied that standard correctly to the evidentiary record. As passionately as the petitioners may feel that they were wronged by Dr. Sweet, MGH, and the Court of Appeals for the First Circuit, the simple fact is that they were not. Had the results of the BNCT trials been different, petitioners would be toasting Dr. Sweet's memory, rather than defaming him before this Court. The court of appeals was right to recognize that the bar to be surmounted in a malpractice case cannot and should not be lowered "to compensate for absence of relevant experience, fading memory, or lack of documentary evidence," and that "[c]onclusory opinions, unattached to predicate evidence of existing standards, cannot fairly fill the void." Pet. App. 35a.

For those reasons, and for all of the reasons set forth above, Elizabeth Dutton Sweet and Frederick H. Grein, Jr., as Representatives of the Estate of William H. Sweet, M.D., respectfully request that the petition for a writ of certiorari be denied.

Respectfully submitted,

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APPENDIX

APPENDIX — TRANSCRIPT OF THE EVIDENCE, SEPTEMBER 29, 1999

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
Civil Action No. 97-12134-WGY

EVELYN HEINRICH, ET AL., PLAINTIFFS

v.

WILLIAM H. SWEET, ET AL., DEFENDANTS

VOLUME 11

BEFORE: The Honorable William G. Young,
District Judge, and a Jury

* * *

[JA 1905]

THE COURT: All right, withdrawn. Won't you let them see it though so then we'll —

MR. FREEMAN: He has it before him.

MR. DOHERTY: Can I take a look at that?

MR. FREEMAN: Oh, certainly.

THE COURT: Go ahead.

MR. DOHERTY: Can I just take a look at it, I'll give it back to him, sir.

THE COURT: Go ahead, Mr. Freeman.

MR. FREEMAN: Thank you, Judge.

Q. I want to show you Exhibit 16. This is one that you said, Mr. Doherty, that you had left up here, and I don't see it.

MR. DOHERTY: Let me make sure that I don't have it.

MR. FREEMAN: Here it is. He's got it.

Q. So, I want to — a moment ago, sir, we looked at the November 2nd, 1960 handwritten note. I now want to draw your attention to a document that was just five days before that, October 28th, 1960, Exhibit 16.

Do you have that in front of you, sir?

A. 16?

Q. Yes, sir. I thought I put that in your hand.

A. I have 15.

[JA 1906]

MR. CLIFFORD: It doesn't have a date on the first page.

Q. There it is.

MR. DOHERTY: Oh. The date's on the second page.

Q. Yes, the date is on the second page, but it is an October 28th, 1960 memo from T. J. Thompson to Dr. Manson Benedict and from which Mr. Doherty questioned you extensively.

Appendix

T.J. Thompson was the director of the reactor facility, wasn't he?

A. Yes.

Q. And Manson Benedict was the secretary of the Reactor's Biomedical Advisory Committee, he was the secretary to that committee, right?

A. And head of the department.

Q. And head of the medical department?

A. No, head of the nuclear engineering department.

Q. Head of the nuclear engineering department. Okay. That's fine.

Now, Dr. Thompson wrote, in the third paragraph: It's my general belief, and I believe it's shared by Dr. Brownell, that we know about as much concerning the neutron and gamma ray dose levels as we will know at any time in the next few months. And he went over that. And I think that's where you said we might as well go ahead and **[JA 1907]** experiment on patients because we weren't going to get an answer to what we didn't know for two decades.

In fact, the medical facility, research facility underneath the reactor, after these BNCT experiments were called off in 1961, wasn't used for any human experiments for 28 years or more, was it?

A. No.

Q. Okay. Now, that paragraph that we're looking at right here says — oh, by the way, and if you'll look at the last page, and you don't have to put this one up, the last page of this shows that you were cc'd with a copy of this letter, right?

A. Yes.

Q. All right. So that if there was something in there that was attributed to your belief which you violently, or in any event, in any way disagreed with you would have brought that to somebody's attention, wouldn't you have?

A. Yes.

Q. Okay. So here it says: It's my general belief, and I believe shared by Dr. Brownell, that we know about as much concerning the neutron and gamma ray dose levels as we'll know at any time in the next few months. By far the greatest unknown factor concerns the biological effects of this type of massive dose on boron-containing tissue.

So it's clear that it wasn't even, nobody was in. . . . **[END OF JA 1907]**

SUPREME COURT, U.S.
FILED
MAY 9 2003
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No. 02-1251

IN THE

Supreme Court of the United States

EVELYN HEINRICH and HENRY M. SIENKEWICZ, JR.,

Petitioners,

v.

ELIZABETH DUTTON SWEET and FREDERICK H. GREIN, JR., Representatives of the Estate of WILLIAM H. SWEET, M.D., and MASSACHUSETTS GENERAL HOSPITAL,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT MASSACHUSETTS GENERAL HOSPITAL

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QUESTION PRESENTED FOR REVIEW

I. Whether this Court should deny the Plaintiffs' Petition for Writ of Certiorari, pursuant to S. Ct. R. 10, based upon the fact that the decision of the Court of Appeals properly stated and applied the appropriate rules of law and standards of appellate review to the issues presented by the Petitioners' and Respondents' cross-appeals from the Judgments entered by the District Court in these actions.

II. Whether the Court of Appeals properly vacated the jury verdicts against the Respondents, Massachusetts General Hospital and William H. Sweet, M.D., and ordered the entry of Judgment in their favor, based upon its determination that the evidence presented at trial was wholly inadequate and insufficient, as a matter of law, to support or uphold the original jury verdicts in favor of the Petitioners.

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B. The Court of Appeals properly vacated the jury verdicts against the Respondents, Massachusetts General Hospital and William H. Sweet, M.D., and ordered the entry of Judgment in their favor, based upon its determination that the evidence presented at trial was wholly inadequate and insufficient, as a matter of law, to support or uphold the original jury verdicts in favor of the Petitioners. 14

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STATEMENT OF THE CASE

This is an action arising out of medical care and treatment provided by the Respondents, Dr. William Sweet and Massachusetts General Hospital, ("MGH"), to the Petitioners' decedents, Eileen Sienkewicz and George Heinrich, more than forty years ago. At the time of their treatment, both Mrs. Sienkewicz and Mr. Heinrich were suffering from a condition known as glioblastoma multiforme, the deadliest form of brain cancer in humans. (JA 4153). Untreated, or even when treated with craniotomy, (surgical removal of tumor from the brain), or conventional radiation, glioblastoma multiforme was invariably fatal, with typical survival times of six to eight months from the date of diagnosis. (JA 4153). It was an incurable disease in 1960, when Mrs. Sienkewicz and Mr. Heinrich were first diagnosed, and it remains an incurable disease today. (JA 2376).

In the early 1950's, Dr. William H. Sweet, the late Chief of Neurosurgery at Massachusetts General Hospital, and other researchers, began working to develop a potential cure for glioblastoma multiforme, through a new method of radiation treatment known as boron neutron capture therapy ("BNCT"). (JA 2962). The theory of BNCT arose out of scientific research relating to nuclear physics and atomic energy conducted in the 1930's. (JA 1063). Physicists had learned that when a boron atom, (number 5 on the table of elements with 5 protons), is subjected to neutron radiation, the boron atom will "split" into two smaller atoms, helium, (number 2 on the table of elements with 2 protons), and lithium, (number 3 on the table of elements with 3 protons), giving off a tiny burst of nuclear energy. (JA 1061-1063).

Dr. Sweet and other medical researchers recognized that if a significant concentration of boron atoms could be introduced into tumor tissue within the brain, and that tumor tissue was then exposed to a beam of neutron radiation, the resulting multiple small bursts of nuclear energy would kill the surrounding tumor cells. (JA 2828-2829). Unlike conventional forms of radiation therapy, slow neutron radiation is low in energy and does not, in and of itself, cause any significant risk of harm to human tissue. (JA 2956-2961). However, when neutron radiation is focused upon tumor tissue containing boron atoms, the neutrons are "captured" by the boron atoms, (causing the split into helium and lithium atoms described previously), and a significant concentration of localized radiation is delivered directly to the tumor tissue. (JA 2828-2833). Dr. Sweet was one of the primary researchers involved in the first clinical trials of BNCT, conducted at the Brookhaven National Laboratories, in New York, in 1950 and 1951. (JA). He continued working to develop and improve BNCT throughout the 1950's, primarily at Brookhaven. (JA 2962-2971).

In 1959 Dr. Sweet began assembling a team of doctors, physicists and chemists to prepare for further clinical trials of BNCT in Massachusetts. The treatment would be provided in a specially designed operating room beneath a new nuclear reactor at the Massachusetts Institute of Technology, (MIT), in Cambridge, Massachusetts. (JA 2971-2980). The reactor was built under the auspices of the United States Atomic Energy Commission and became operational in 1958. (JA 4023-24). Mrs. Sienkewicz and Mr. Heinrich had been diagnosed with glioblastoma multiforme in 1960. They were provided an opportunity to participate in the program and receive BNCT at the MIT facility. In view of the fatal nature of their disease, and with no other effective treatment options available to them, Mrs. Sienkewicz and Mr. Heinrich agreed to participate in the

clinical trials, in the hope that BNCT could potentially cure their disease, or at least prolong their lives.[1] (JA 1222-1230).

Prior to the start of the clinical trials at MIT, Dr. Sweet's team conducted extensive animal studies and evaluated more than 145 potential boron compounds to determine the best compounds to be used when the trials began upon patients. (JA 1851, 2231-45, 2270-73, 2336-39). Dr. Sweet's team also built upon extensive research conducted by others, including quantitative studies of the effects of ionizing radiation on monkeys, rabbits, and mice and of the destruction of animal tumors using BNCT. (JA 3901-02).

On November 13, 1960, Mrs. Sienkewicz became the first patient to receive BNCT in the clinical trials at MIT. (JA 2866, 2977). Almost four months later, on March 4, 1961, x-ray studies showed that she had "no definite diagnosis of recurrent tumor." (JA 6372). However, in August of 1961 she was found to have recurrence of her tumor. (JA 6365). Mrs. Sienkewicz was admitted to MGH in September 1961. She died on October 31, 1961, almost seventeen months after her initial diagnosis of glioblastoma multiforme and almost one year after undergoing BNCT. (JA 6365-66).

George Heinrich was the sixth patient to receive BNCT during the clinical trials at MIT. (JA 2882). He had been diagnosed with a glioblastoma multiforme in October, 1960. (JA 6082, 6305). Attempts at surgical removal of the tumor and conventional radiation were ineffective, with the tumor

---

1. Although the plaintiffs claimed that Mrs. Sienkewicz and Mr. Heinrich were not fully informed of the risks attendant to the treatment, the jury found in favor of Dr. Sweet and MGH on the plaintiffs' claims alleging lack of informed consent. (JA 177-179).

growing back after only a few weeks. (JA 6097, 6123). Mr. Heinrich received BNCT at the MIT facility on January 18, 1961, approximately two months after Mrs. Sienkewicz had received her treatment. (JA 2882). (As of that time, Mrs. Sienkewicz appeared to be doing well, with no evidence of recurrence of her tumor). (JA 6372). Unfortunately, BNCT did not appear to have any significant beneficial effect upon Mr. Heinrich's tumor. In April, 1961, a brain scan showed apparent recurrence of the tumor. He died on May 27, 1961. (JA 6307).

A total of sixteen patients received BNCT between November, 1960, and August, 1961, at the MIT reactor. Despite initial optimism, based upon the results first experienced by Mrs. Sienkewicz, all of the patients eventually died. (JA 3915). Autopsy findings and subsequent research eventually demonstrated that although the BNCT had been effective in destroying tumor tissue, it also caused unanticipated damage to adjacent blood vessels, apparently due to a sequestering of the boron compound within the walls of the vessels, resulting in selectively high doses of radiation to those vessels. (JA 2850). This complication was not known (and, logically, could not have been known), until after the conclusion of the clinical trials and the review and analysis of the autopsy results of the sixteen patients. (JA 1903-04, 2282-83, 2286-88, 2349). The results of the autopsy studies were first presented at a conference in 1964. They were first published in 1972, in what has become known as the Asbury Article, written by a Dr. Arthur Asbury, along with Dr. Sweet, and introduced as Exhibit 1 at the trial of this case in the District Court. (JA 0844, 2832-38, 2851-52).

Thirty four years after Mrs. Sienkewicz and Mr. Heinrich died, attorneys representing their estates filed a class action

in the United States District Court for the Eastern District of New York. In the eleven-count Complaint they asserted claims for alleged violations of constitutional and civil rights under the *Bivens* doctrine, civil fraud, battery, intentional infliction of emotional distress, strict liability for inherently dangerous activities, personal injury caused by exposure to toxic substances, lack of informed consent, wrongful death, "civil responsibility for crimes against humanity," negligence, and negligent misrepresentation. On August 20, 1997, Judge Hurley of the Eastern District of New York ordered the case transferred to the District of Massachusetts, where it was initially assigned to Judge Wolf on September 25, 1997. (JA 5).

Thereafter, the defendants filed various motions to dismiss the actions. The motions were scheduled for hearing on March 18, 1999, before Judge Wolf. (JA 11). However, on March 1, 1999, the case was reassigned to Chief Judge William Young. (JA 11). Judge Young ordered that the case would proceed to trial in six months, despite the fact that no discovery had been conducted by any of the parties, due to an agreement by the parties to stay discovery until after the court decided the motions to dismiss. (JA 11).

Trial was scheduled to begin on September 10, 1999. Based upon various rulings and decisions of the District Court prior to trial, the plaintiffs' only remaining causes of action, as of September 1, 1999, were their *Bivens* claims, under federal law, and their Massachusetts state law claims for negligence, wrongful death and lack of informed consent. On September 9, 1999, one day prior to opening statements, the Court heard argument upon the defendants' motions for Judgment as a Matter of Law, (JA 396-460), and allowed those motions as to all of the plaintiffs' federal Civil Rights claims under *Bivens*. (JA 460). Consequently, the only matters

presented to the jury at trial were state law claims under Massachusetts law.

The jury heard evidence over fourteen days, between September 10 and October 7, 1999. During trial, the plaintiffs called two expert witnesses to provide testimony in support of their claims. Dr. Larry Junck, a neurologist and neuro-oncologist, was their only medical expert. (The plaintiffs' second expert, Dr. Michael Grodin, described himself as a medical ethicist). The only testimony provided by Dr. Junck as to the plaintiffs' claims of negligence, wrongful death and lack of informed consent was his personal opinion that the decision to proceed with BNCT, without knowledge of all the potential risks was "irresponsible" and "inappropriate." (JA 985:11-987:21) (see also JA 988:25-989:13). Dr. Junck was never asked to provide an expert opinion specifically directed to the question of whether the defendants deviated from the applicable standards of care in 1960. (JA 1116, 1129). Such expert testimony is required under Massachusetts law, in order for a plaintiff to establish claims of medical negligence and/or wrongful death and in order for the Court to submit those claims to the jury for consideration. *Brune v. Belinkoff*, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968). In addition, Dr. Junck admitted during cross examination, that it was impossible for him to say whether BNCT *hastened* the deaths of either Mrs. Sienkewicz or Mr. Heinrich in any way. (JA 945-946, 952-954, JA 1116 and 1129). Under Massachusetts law, in order to recover damages in an action alleging wrongful death, a plaintiff must prove that the alleged negligence hastened the death of the plaintiff's decedent. *Edwards v. Warwick*, 317 Mass. 573, 577-578, 59 N.E.2d 194, 196 (1945)

Dr. Grodin 's testimony related primarily to the plaintiffs' claims for lack of informed consent. The jury ultimately found in favor of Dr. Sweet and MGH on those claims. (JA 177-79). Neither Dr. Junck nor Dr. Grodin ever provided any testimony that Dr. Sweet violated any standards of care of the average qualified neurosurgeon practicing in 1960 or 1961.[2] (JA 924-1196).

During trial, Judge Young determined, over the defendants' objection, that he would instruct the jury under the 1995 version of the Massachusetts wrongful death statute, rather than the version of the statute in effect at the time of the treatment and the deaths in 1960 and 1961. (Pet. App. 37a-72a). On October 15, 1999, the jury found in favor of the defendants as to the plaintiffs' claims alleging lack of informed consent, but found in favor of the plaintiffs, on the negligence/wrongful death claims, awarding compensatory damages of $3,000,000 and punitive damages of $5,000,000. (JA 177-179). Dr. Sweet and MGH filed timely motions for judgment as a matter of law and/or for a new trial.

On September 29, 2000, Judge Young issued a written opinion, reversing his earlier decision than the 1995 version the Massachusetts wrongful death statute applied to this action, ruling that the 1960-61 version of the statute applied. (Pet. App. 37a-72a). This decision reduced the compensatory and punitive damage awards for wrongful death to $20,000, (reducing the overall award of damages from $8,000,000 to approximately $800,000). The Court otherwise denied the post-trial motions, without issuing a written opinion or providing any specific rulings from the bench setting forth

2. The Plaintiffs only direct claims of negligence and wrongful death were against Dr. Sweet. The claims against MGH were for vicarious liability based upon the alleged liability of Dr. Sweet.

its reasons for its denial of the motions. The parties filed timely cross appeals from the jury verdicts, from the Trial Court's rulings and from the Judgments.

In an opinion issued on August 27, 2002, the Court of Appeals for the First Circuit vacated the Judgments in their entirety, ruling that Judgment should have been entered for Dr. Sweet and MGH as a matter of law, because plaintiffs had failed to present legally sufficient evidence to support their negligence and wrongful death claims:

REASONS FOR DENYING THE WRIT

A. The Plaintiffs' Petition does not present issues that warrant review by this Court, because the decision of the Court of Appeals properly stated and applied the appropriate rules of Massachusetts law and the correct standards of appellate review to the issues presented by the Petitioners' and Respondents' cross-appeals.

Rule 10 of this Court states that "[a] petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." That language was added by an amendment to the Rule in 1995, acknowledging the well recognized principle that "[t]he Supreme Court is not, and never has been, primarily concerned with the correction of errors in lower court decisions." *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting) (*quoting* Address of Chief Justice Vinson before the American Bar Association, Sept. 7, 1949). The Court's function is "to resolve conflicts of opinion on federal questions that have arisen among lower courts, to pass upon questions of wide import under the Constitution, laws, and treaties of the United

States, and to exercise supervisory power over the lower federal courts." *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting).

The decision of the Court of Appeals in the present action does not conflict with any prior decisions of this Court or of the Courts of Appeals of any other circuit. Moreover, Petitioners' contention that the Court of Appeals misstated the applicable standard of review is simply not correct. The First Circuit's decision is essentially nothing more than an evaluation of the sufficiency of the evidence presented at trial, in relation to well established principles of Massachusetts law pertaining to claims of medical negligence and wrongful death. As Justice Taft stated in *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387 (1923),

> it is very important that we be consistent in not granting the writ of certiorari except in cases involving principles the settlement of which is of importance to the public as distinguished from that of the parties, and in cases where there is a real and embarrassing conflict of opinion and authority between the circuit courts of appeal.

Layne & Bowler Corp. v. Western Well Works, Inc., 261 U.S. 387, 393.

The Petitioners have referenced the language of Rule 10 in their Petition and appear to acknowledge that it poses a substantial obstacle to the review they seek from this Court. (Pet. Br. at 6). In an effort to overcome this obstacle, the Petitioners contend that the decision of the Court of Appeals created and applied a new standard for appellate review of a trial court's denial of a motion for judgment as a matter of

law. (Pet. Br. at 6-7). This contention is contrary to the clear language of the Court's decision. The Court of Appeals stated the appropriate standard of review in its decision when Judge Lynch wrote:

> We review de novo a district court's denial of a Rule 50 motion for judgment as a matter of law. But "our review is weighted toward preservation of the jury verdict," *Rodowicz*, 279 F.3d at 41, and "we must affirm unless the evidence was 'so strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them," *Walton v. Nalco Chem. Co.*, 272 F.3d 13, 23 (1st Cir. 2001) (*quoting Negron v. Caleb Brett U.S.A., Inc.*, 212 F.3d 666, 668 (1st Cir. 2000).

Heinrich v. Sweet, 308 F.3d 48, 59-60 (1st Cir. 2002); (Pet. App. 14a).

The Petitioners claim that this statement by the Court of Appeals "is at odds with the teachings of this Court, the other circuits and the Commonwealth of Massachusetts." They go on to contend that by enunciating this standard, the Court of Appeals was then free to ignore the evidence presented at trial and to "substitute its own conclusions for those of the jury." (Pet. Br. at 7). MGH respectfully submits that the Petitioners' argument is an obvious mischaracterization of the decision by the Court of Appeals. The standard presented and followed by the Court of Appeals is well established and entirely in accordance with prior decisions of this Court and of the other circuits.

In *Walton v. Nalco Chemical Co.*, 272 F.3d 13 (1st Cir. 2001), the Court stated:

> Judgments entered as a matter of law are reviewed *de novo*, and will be affirmed "only if, after scrutinizing the proof and inferences derivable therefrom in the light most hospitable to [the plaintiff], we determine that a reasonable factfinder could have reached but one conclusion: that [the defendant] w[as] entitled to judgment."

Walton, 272 F.3d at 18. In fact, the Petitioners themselves acknowledged the propriety of this standard of review in their Consolidated Brief in Opposition to the briefs filed by the Respondents in the Court of Appeals, stating: "The district court may grant a motion for judgment notwithstanding the verdict only upon its determination that the evidence could lead a reasonable person to only one conclusion." *Plaintiffs-Appellees' Consolidated Brief in Opposition to Briefs of Defendants-Appellants William H. Sweet, M.D. and Massachusetts General Hospital*, at 4-5. The statement by the Court of Appeals, that it could only vacate the jury verdicts if the evidence was "so strongly and overwhelmingly inconsistent with the verdicts that no reasonable jury could have returned them," established perhaps the most stringent standard that an appellate court may apply when reviewing an issue on appeal. It is hardly a standard that would permit the Court of Appeals to ignore the evidence and substitute its own judgment for that of the jury, as the Petitioners suggest.

The Petitioners also contend that the Court of Appeals failed to consider all of the evidence presented at trial in the District Court, as required in accordance with this Court's

decision in *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133 (2000), ("in entertaining a motion for judgment as a matter of law, the court should review all of the evidence in the record."). *Reeves*, 530 U.S. at 150. MGH maintains that the Petitioners' argument in support of this assertion amounts to nothing more than conjecture and speculation. The language of the written decision by the Court of Appeals demonstrates a comprehensive, careful and detailed evaluation of all the evidence and a clear understanding by Judge Lynch of the numerous and complex factual, procedural, medical and technical aspects of the evidence and the proceedings in the Trial Court. One cornerstone of the decision by the Court of Appeals is its determination that "[t]here is *no evidence at all* in the record that BNCT hastened decedents' deaths." 308 F.3d at 61 (emphasis added). An example of the Court's careful consideration of the District Court record is its evaluation of the evidence relating to the question of whether BNCT hastened the deaths of Mrs. Sienkewicz or Mr. Heinrich. Despite the fact that the Plaintiffs only medical expert, Dr. Larry Junck admitted unequivocally during cross-examination that he could *not* state that the administration of BNCT hastened the deaths of either Mrs. Sienkewicz or Mr. Heinrich *in any way*,[3] the Court

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3. When Dr. Junk was questioned as to whether BNCT hastened the deaths of either patient he testified:

> A. I think it would be very difficult for me to say what would have happened had they not received that treatment. That would be *just hypothetical* and is just the kind of thing that I would *have no basis for saying* what would have happened had they not received BNCT and perhaps received some other treatment.

(Cont'd)

of Appeals nevertheless undertook a detailed evaluation of the multiple, random references to various other aspects of the evidence identified by the Petitioners in their efforts to counter this apparently fatal admission by Dr. Junck. Throughout its opinion the Court of Appeals demonstrated that it clearly conducted a thorough examination of the issues raised by the Petitioners and the various evidentiary references offered by the Petitioners in support of their claims. The Court simply found that the evidence presented at trial was insufficient in certain crucial respects to establish the requisite elements of the Petitioners claims. The Petitioners were required to prove those elements, pursuant to well established principles of Massachusetts law, in order for the trial judge to permit their claims to be submitted to the jury. *See* 308 F.3d at 64-68; (Pet. App. 23a-30a).

(Cont'd)

Q. Or perhaps received no treatment whatsoever?

A. Perhaps.

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Q. But you certainly *cannot say* that the administration of BNCT *in any way hastened* [Sienkewicz's] *death*, is that correct?

A. *That's correct.*

Q. And *you cannot say* that the administration of the BNCT *in any way hastened* George Heinrich's *death*, is that correct?

A. *That's correct.*

(JA 1116:10-20) (emphasis supplied).

B. The Court of Appeals properly vacated the jury verdicts against the Respondents, Massachusetts General Hospital and William H. Sweet, M.D., and ordered the entry of Judgment in their favor, based upon its determination that the evidence presented at trial was wholly inadequate and insufficient, as a matter of law, to support or uphold the original jury verdicts in favor of the Petitioners.

1. The Negligence Claims

As discussed previously, Dr. Larry Junck was the only expert presented by the plaintiffs at trial who was permitted to offer expert opinion testimony concerning the plaintiffs' negligence and wrongful death claims. However, Dr. Junck's testimony did not establish an appropriate basis for submission of the negligence and/or wrongful death claims to the jury, because Dr. Junck never stated that Dr. Sweet's treatment of either Mr. Heinrich or Ms. Sienkewicz deviated from the standard of care of the average qualified neurosurgeon practicing in 1960 and 1961. *Brune v. Belinkoff*, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968); *Rogers v. Okin*, 478 F. Supp. 1342, 1384-85 (1979); *Stepakoff v. Kantar*, 393 Mass. 836, 840, 473 N.E.2d 1131, 1135 (1985). The *Brune* standard has remained the unaltered and well recognized criteria under Massachusetts law upon which the jury is to assess a physician's conduct and upon which the Court is to assess the sufficiency of a medical expert's testimony, in order to determine whether the claims warrant submission to the jury. Expert testimony is generally required in order for a plaintiff to meet the burden of proof established under *Brune*. As the Massachusetts Supreme Judicial Court stated in *Forlano v. Hughes*, 471 N.E.2d 1315 (Mass. 1984):

> It is only in exceptional cases that a jury instructed by common knowledge and experience may

> without the aid of expert medical opinion determine whether the conduct of a physician toward a patient is violative of the special duty which the law imposes as a consequence of this particular relationship.

Forlano v. Hughes, 471 N.E.2d 1315, 1319 (Mass. 1984).

Although Dr. Junck was not required to state his opinions in formulaic terms, tracking the exact language of the *Brune* decision, the plaintiffs *were* required to illicit at least some testimony from Dr. Junck focused upon the criteria presented in *Brune*. Dr. Junck's only testimony even approaching the *Brune* standard was his personal belief that the decision to proceed with BNCT, without knowing all of the potential risks to the patients, was "irresponsible" and "inappropriate." (JA 985:11-987:21) (see also JA 988:25-989:13). However, as noted by the Massachusetts Appeals court in *Broderick v. Gibbs*, 1 Mass. App. Ct. 822, 296 N.E.2d 708 (1973) (rescript opinion), testimony that amounts to nothing more than a difference of opinion concerning the advisability of a procedure, does not establish a departure from the standard of care. *Id.*, at 822. Since Dr. Junck's criticism of BNCT was not stated, either specifically or generally, in terms of the applicable standard of care under *Brune v. Belinkoff*, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968), his opinions were insufficient as a matter of law.

Moreover, Dr. Junck's theory of liability was inconsistent with the jury's verdict in favor of the defendants on the plaintiffs' claims for lack of informed consent. MGH does not suggest that a jury verdict in favor of a physician as to informed consent would always be inconsistent with a negligence verdict against the physician. In the present case,

however, Dr. Junck's theory as to the *negligence* claims was premised exclusively upon the contention that the defendants should not have proceeded with the BNCT trials at all, due to the fact that they did not know, and indeed, could not know all of the risks, prior to initiating the treatment. The *informed consent* claims were similarly premised on the contention that the defendants failed to "disclose in a reasonable manner all significant medical information that the physician possesses . . . or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." (JA 2601:10-16). The jury verdict in favor of the Respondents on the claims for lack of informed consent effectively established that Dr. Sweet was aware of all the information which a reasonable physician in his specialty should have possessed at that time and that he disclosed all such "significant medical information" to his patients. The criticism offered by Dr. Junck cannot logically or reasonably be deemed to establish the appropriate standard of care governing Dr. Sweet's conduct relative to a claim of medical negligence, because it would impose a finding of negligence upon every doctor providing any new treatment or medication, unless all of the risks of that treatment or medication were know. If Dr. Junck's theory of liability as to the Petitioners negligence claims were permitted to stand, then any doctor involved in clinical trials of a new type of treatment or a new medication, could be found negligent simply for proceeding with that new treatment or medication before it had developed to a point where all of the potential risks were known and could be disclosed to the patient. A doctor could not avoid liability on a subsequent claim of negligence even if that doctor informed the patient of all the known risks, explained that other potential risks were not yet known and explained that the full extent of those unknown

potential risks could only be determined by proceeding with the clinical trials. As a matter of public policy, such a standard could certainly have a chilling effect upon clinical trials of any new form of treatment or medication.

2. The Wrongful Death Claims

The Court of Appeals also ruled that the plaintiffs' claims for wrongful death should not have been presented to the jury, because the plaintiffs failed to offer any expert testimony to establish that the alleged acts or omissions of Dr. Sweet hastened the deaths of the decedents in any way. Although the plaintiffs' expert, Dr. Junck testified, over objection, that in his opinion the BNCT *caused* the deaths of Mrs. Sienkewicz and Mr. Heinrich, he also admitted that it was impossible to say whether the BNCT hastened the deaths of either Mrs. Sienkewicz or Mr. Heinrich, due to the fact that they would have died from their glioblastoma multiforme irrespective of whether they did or did not receive BNCT. (JA 945-946, 952-954, 1116 and 1129). The elements of compensable damages set out in the Massachusetts wrongful death statute permit a jury to award damages only for the *loss* of the decedent's care, comfort, guidance, support and other benefits resulting from the decedent's death. (JA 2610-2611). If the defendant's conduct did not hasten the death some way, the plaintiffs cannot be found to have lost any time with the decedent, during which the plaintiff could have enjoyed the benefits addressed under the statute. Under Massachusetts law, hastening of death must be established through expert testimony. *Edwards v. Warwick*, 317 Mass. 573, 577-578, 59 N.E.2d 194, 196 (1945). Without such expert testimony, any other evidence relied upon by the plaintiffs as constituting support for their wrongful death claims, must be considered insufficient as a matter of law.

Civatarese v. Gorney, 358 Mass. 652, 656, 266 N.E.2d 668, 671 (1971) (holding expert testimony necessary to establish causation in medical malpractice case).

During his pre-charge to the jury on September 10, 1999, and his final charge to the jury on October 8, 1999, Judge Young instructed the jurors that in order to establish their claims for wrongful death, the plaintiffs were required to demonstrate that the defendant's negligence shortened the lives of the decedents. (JA 2610-2611) This portion of the charge was in accordance with the case law of Massachusetts. *Walker v. Gage*, 223 Mass. 179, 182, 111 N.E. 766 (1916); *accord Corriveau v. United States*, 832 F. Supp. 19, 23 (D. Mass. 1993) (applying Massachusetts law); *Edwards v. Warwick*, 317 Mass. 573, 577-578, 59 N.E.2d 194, 196 (1945) and cases cited. Plaintiffs' counsel did not object to this portion of the charge. Although counsel for the Plaintiffs suggested to the Court that punitive damages could be awarded without the jury finding that BNCT hastened the deaths, he did not challenge the legal accuracy of the charge as to the plaintiffs' burden of proving hastening of the deaths. The Court did not revise any aspect of the charge based upon this suggestion by plaintiff's counsel. (JA 2619-2620).

In *Edwards v. Warwick*, the Supreme Judicial Court of Massachusetts held that "[r]ecovery may be had where there is substantial ground for a finding that the negligence has caused death to occur when it did, even though it would have occurred at no very remote date from other causes." *Edwards* 317 Mass. at 578, 59 N.E.2d 194, 196. In *Edwards*, there was testimony from a medical witness who treated the decedent before the accident and had seen her afterwards. He gave his opinion that her death was "hastened prematurely by the accident." *Edwards*, 317 Mass. at 577, 59 N.E.2d at 196. The Massachusetts Supreme Judicial Court ruled that:

> . . . in view of testimony of persons intimate with the deceased from which the jury could have found that there was a marked deterioration in her general health immediately following the accident . . . and in view of the definite opinion of the medical witness . . . we think that the jury could find that the accident had caused the death of the testatrix at an earlier date than that at which it would have come about from other causes. Such finding is not precluded by the fact that no witness attempted to testify by just how much death had been accelerated.

Edwards, 317 Mass. at 577-578, 59 N.E.2d at 196 (emphasis supplied).

Generalized references by Plaintiffs' counsel, during closing argument, to statistics regarding survival times for patients with glioblastoma multiforme, described in various journal articles that were never supported by expert testimony at trial as to their reliability or applicability to either Mrs. Sienkewicz or Mr. Heinrich, (JA 2675, 2691), are entirely insufficient to meet the plaintiffs' burden of proof as to hastening of death. (JA 945-946, 952-954, JA 1116 and 1129). The Court of Appeals correctly determined that the Plaintiffs did not present sufficient evidence at trial from any expert witness to establish that BNCT hastened the deaths of Mrs. Sienkewicz or Mr. Heinrich. Absent competent evidence of hastening of death, the plaintiffs' claims for wrongful death failed as a matter of law.

C. The Plaintiffs' Petition contains numerous misstatements of the evidence

MGH disputes the Petitioners' assessment of the accuracy and propriety of the decision by the Court of Appeals and submits that the accusatory language used by the Petitioners in criticizing the Court of Appeals is inappropriate. Statements made by the Petitioners relating to the evidence are equally inappropriate, with only minimal citation to specific pages of the Joint Appendix. The entire Petition contains only twenty such references to the Joint Appendix. Of the 6,693 pages contained in the Joint Appendix, the twenty references offered by the Petitioners pertain to only 36 pages of the record, 7 of which relate simply to a conference between counsel and the trial judge and the Court's instructions to the jury, rather than to actual testimony presented at trial. MGH recognizes that the Petitioners are not required to document all factual references with citations to the Joint Appendix. However, where their arguments are based upon issues of the sufficiency of the evidence, their failure to document the alleged evidence is indicative of the lack of such evidence. The Petitioners contend that there is "overwhelming evidence", (Pet. Br. at 21), to support their claims, without providing sufficient citation to those sections of the Joint Appendix where such overwhelming evidence might be found.

The most extreme example of the Petitioners' failure to provide supportive references is their repeated suggestion that the Defendants *knew*, prior to providing BNCT to Mrs. Sienkewicz and Mr. Heinrich, that it would cause them harm and would not provide any therapeutic benefits. At page 6 of the Petition, they state that the "Defendants' employees" testified that "they had *knowingly* violated the standard of

care in the interest of expediency." (Emphasis supplied). The Petitioners have offered no actual quotations of this supposed testimony or any references to the Joint Appendix to support this assertion. MGH submits that the statement is not accurate. On pages 8 and 9 of the Petition, the Petitioners state that the Defendants "understood" that retained boron in the cell walls of healthy blood vessels would cause damage to those vessels, but that the defendants "decided to forge ahead, in the interest of saving time". Again, the Petitioners fail to provide any references on pages 8 or 9 of the Petition to actual evidence that might support this contention. The Petitioners' assertion is incorrect. In fact, the evidence presented at trial, particularly a medical article, (the Asbury article), published in 1972 and introduced by the Plaintiffs as Exhibit 1 at trial, demonstrated that Dr. Sweet did not become aware of complications associated with retained boron in the cell walls of the blood vessels until *after* the conclusion of the BNCT clinical trials at MIT. Moreover, this problem was only identified as a result of the autopsy findings of the patients who had participated in those trials. (JA 2828-2853).

The decision of the Court of Appeals also noted that, "some of Dr. Junck's opinions rested on particular data or publications that do not support his conclusions and *have been mischaracterized by plaintiffs in their briefs to us*." (Pet. App. at 24a-25a). (Emphasis supplied).

A final example of a mis-statement of the evidence in the Petition is the assertion made in footnote 14, on page 22 of the Petition, where the Petitioners assert:

> The Panel ignores *all of the Plaintiffs' evidence* that (Mrs. Sienkewicz's) earlier craniotomy had left her *without tumor* at the time of the BNCT

(Emphasis supplied). Footnote 14 does not contain any reference to the pages of the Joint Appendix that contain "*all of*" this evidence relied upon by the Petitioners. Counsel for the Plaintiffs first attempted to raise this argument, unsuccessfully, near the end of trial, during cross-examination of Gregory Koski, M.D., an MGH witness. (JA 2159-2163). However, during the pre-charge conference, the Court instructed plaintiffs' counsel that he was not permitted to argue in his closing that Mrs. Sienkewicz did not have glioblastoma multiforme when she received BNCT, because there was no evidence to support that suggestion. (JA 2345 and 2553-2554).

CONCLUSION

The arguments presented by the Petitioners concerning the decision of the Court of Appeals in this case do not warrant further appellate review by this Court. The Petitioners have not raised any legitimate "questions of wide import under the Constitution, laws, (or) treaties of the United States", *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting). No aspect of the decision of the Court of Appeals involves a conflict of opinion on a federal question among any of the lower federal courts. In fact, the decision does not involve any issues of *federal law*. The only claims presented to the jury at trial in this matter were *state law* claims, for alleged negligence, alleged wrongful death and an alleged failure to obtain informed consent. The case was decided upon principles that are well settled under the laws of the Commonwealth of Massachusetts and do not require consideration by this Court.

The decision of the Court of Appeals was simply an evaluation and assessment of the sufficiency of the evidence presented at trial, with reference to specific elements that the Plaintiffs were required to prove in order to warrant submission of their claims to the jury. The errors asserted by the Petition relate to factual issues and the application of properly stated principles of Massachusetts law to those factual issues. Consequently, the Petitioners' arguments fall squarely within the language of Rule 10 of this Court, which states: "[A] petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law."

MGH submits that the review requested by the Petitioners would require a complete re-evaluation by this Court of the same evidence within the Joint Appendix evaluated by the Court of Appeals. The Petitioners have provided limited and insufficient citations in their Petition to the actual evidence in the Joint Appendix. The decision of the Court of Appeals demonstrates clearly that it performed a careful, detailed and complete review of that evidence and applied the correct rules of law under the correct standards of review. MGH requests that this Court deny the Petition.

Respectfully submitted,

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